Utilization and utility of diagnostic imaging

Quantitative studies and normative considerations

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ABSTRACT

Today the practice of most medical disciplines is almost unrecognisable without modern radiology. Imaging technology is fascinating, is developing rapidly, and is without doubt beneficial, but there are also concerns about over-utilization, the risks of harm and the costs involved.

The overall aim of this dissertation is to improve our understanding of utilization of radiological services, by investigating aspects of the actual use and as perceived by the radiologist. Further, the aim is to illuminate utility issues based on empirical research.

The utilization of imaging was investigated through two quantitative surveys. We collected activity data from all radiology institutions in Norway in order to estimate the frequency of radiological examinations. A questionnaire was mailed to Norwegian radiologists to obtain information about their perceptions, actions and reasoning regarding utilization of imaging.

We found a significant increase in utilization of diagnostic imaging, especially MRI and CT examinations, leading to a relatively high increase in the collective effective dose. We found that geographical variation in examination frequency was highest for these newer technologies. Accessibility is a likely explanation for both the increase in utilization over time and the geographical variation.

According to the radiologists, the major causes of increasing utilization were related to ‘supply and demand’ mechanisms, like expanded technological and medical possibilities, availability of services, and the demands of people and referring clinicians for assurance. They consider over-utilization to comfort patients and clinicians to be the main cause of unnecessary examinations, followed by insufficient referral information. Almost all radiologists reported that they frequently took action in response to inadequate referrals, mainly by contacting the clinician and by checking the medical records. Such actions were primarily motivated by patient safety considerations (risk of complications, radiation dose and low patient age), while somewhat hindered by respect for the judgment of the referrer, the wishes of the patient and practical obstacles.

The empirical findings indicate benefits of increasing utilization of imaging in the shape of improved health outcome, reduced pain and lower costs, but also lack of such benefits and possible harm. The overall usefulness of increased utilization can be considered to be limited from a utilitarian perspective. Norms and measures to manage utilization of imaging initiated by the professionals are those that should have the highest potential for increasing the utility of services. Key elements of such measures should be clinical guidelines, giving radiologists more discretionary power, and critical assessment of referrals.

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CONTENTS

LIST OF ARTICLES

This dissertation in based on the following articles:

I. Børretzen I, Lysdahl KB, Olerud HM. Diagnostic radiology in Norway Trends in examination frequency and collective effective dose. Radiation Protection Dosimetry 2008;124(4): 339-47.

II. Lysdahl KB, Børretzen I. Geographical variation in radiological services: A nationwide survey. BMC Health Services Research 2007;7:21.

III. Lysdahl KB, Hofmann B. What causes increasing and unnecessary use of radiological investigations? a survey of radiologists' perceptions. BMC Health Services Research 2009, 9:155.

IV. Lysdahl KB, Hofmann MB, Espeland A. Radiologists' responses to inadequate referrals. European Radiology 2010, 20(5): 1227-33.

1 INTRODUCTION

I will start this thesis about diagnostic imaging by explaining how fascinating this technology is, and (despite or perhaps for this reason) why it is interesting to investigate aspects of its utilization and utility. By *utilization* I mean the use rates of imaging services and *utility* is used here as the state of being useful to some valuable end, like accurate diagnosis. [1] I then outline the study aims before presenting the background (empirical, theoretical and conceptual) on which the current research is built and motivated. This chapter will include arguments for the main choices of perspective in this dissertation.

1.1 Radiological technology – a commonplace wonder

It is not very long ago that looking inside the living body seemed an absurd idea [1]. When Wilhelm Conrad Röntgen discovered X-rays in 1895, it created an enthusiasm we hardly can imagine: "The earlier, opaque world so full of mysteries on every level – anatomical, sexual and mental – began to dissolve when X-ray mania swept the West" [1, p. 2]. The medical community almost immediately became aware of the value of these mysterious rays for diagnostic and therapeutic purposes, and after a couple of decades the technology was a "commonplace wonder" [1]. Doctors no longer had to rely only on external signs and patient history, but could see pathologic processes directly (as grey shadows on a photographic film). A radiologic aphorism was born: "One look is worth a thousand listens" [2].

The invention of computers in the late 1960s enabled great progress in imaging technology [1]. In turn, computed tomography (CT), ultrasonography (US), magnetic resonance imaging (MRI), and most recently, single photon emission computed tomography (SPECT), positron emission tomography (PET) and cross fusion modalities such as PET/CT were introduced. These scanning techniques reconstruct slices of the body, can create three-dimensional images [1] and have replaced obsolete examination technologies (e.g. lymphangiography), which were invasive, difficult to perform, time consuming and painful/uncomfortable for the patient. The refinement of these technologies is an ongoing process. Capacity is constantly being improved by faster imaging machinery (e.g. the recent multidetector row CT), improving diagnostic accuracy and allowing us to detect diseases with unprecedented detail (down to

[1] The concept of utility, and related terms, are outlined in Section 1.7.

fractions of a millimetre), including functional processes in the body prior to anatomic changes.

Without doubt, radiological technology has “revolutionized the practice of medicine” [3], and most medical disciplines today would be almost unrecognisable in the absence of modern imaging [4]. In addition to enabling us to exclude, detect or gauge the extent of diseases (even at early presymptomatic stages), radiological technology is important in assessing responses to therapy and can reliably detect recurrences [2]. To illustrate:

> “CT can depict lung cancer, guide the biopsy of lesions, help in assessing the spread of the disease elsewhere in the body, help determine response to chemotherapy, and aid in monitoring the patient for the return of disease [2].

Moreover, the use of radiological technology is not restricted to diagnostic purposes; it is increasingly used in treatment to support or replace traditional technologies (e.g. coronary artery bypass surgery). Ultimately diagnostic imaging has improved the patients’ health and life [3], also by safer and less invasive health care services (e.g. replacing exploratory surgery). So when imaging services are used “responsibly and properly, patients’ benefit and society benefits by having higher quality health care available at lower costs” [5].

1.2 Why study the utilization of imaging

> “Radiology has seen enormous growth since the 1960s. Many practices and types of equipment that are now commonplace did not exist a generation ago. Yet the ethical basis for these practices has not seen a corresponding level of engagement” [6].

The main reason for investigating the utilization of diagnostic imaging is that such an amazing and impressive technology may be particularly at risk of being overutilized. [2] A too eager application of imaging may compromise the utility of the services, the benefits may easily be overestimated and the risks and costs somewhat neglected. Excessive testing are said to create “a dual illusion: Abnormalities seem ever more common, and our treatments for them seem ever more effective. These illusions reinforce the habit of doing tests, creating a vicious cycle” [8, p. 37]. This is because increased capabilities of the tests increases the observed prevalence of disease and shift the spectrum of detected disease into milder cases (subtler abnormalities, smaller lesions, earlier stages) which apparently improves the outcome

[2] I will return to the meaning of concepts like over-utilization in the context of diagnostic imaging. In general over-utilization is defined as “use in excess of some optimal, preferred, stipulated (and so on) rate” [7, p. 359].

for patients, with or even without treatment [9]. These apparent improvements reinforce increased intensity of testing and lower treatment thresholds [9,10].

Concern about overuse of imaging is not new. In the United States it was an issue in professional journals in the 1970s [11,12]: X-ray examinations were reported to be "regularly performed when an accurate diagnosis can be made with the naked eye, ear or finger", and the final responsibility for wasted x-rays was placed on the radiologists [12]. The problem of overuse seems to be persistent [13-15], perhaps increasing as diagnostic imaging (with its visual power) tends to replace traditional history taking and physical examination of the patient [2,4]. The extent of overuse can be indicated by studies of referral quality, where approximately 30% of requests are reported to be not in accordance with clinical guidelines when a variety of examinations are studied [16,17]. Other estimations of the proportion of examinations that cannot be justified on clinical grounds vary from 20-50% [18]. A recent Swedish study found that approximately 20% of all CT examinations were not justified [19].

It is claimed that a major challenge in today's health care delivery is that *more* is not necessarily *better* and may in fact be worse: the "paradox of the plenty" [20]. A *risk* of special concern in diagnostic imaging is radiation-induced cancer. The strange ability of radiation both to cure and to cause tumours was known almost from the very beginning [1], and has been a concern in the radiology environment ever since. Not to expose patients to unnecessary risk is a core obligation for professionals according to basic radiation protection policy and legislation [21,22]. The moral requirement that the benefits of health services shall outweigh the risks to the individual patient may be challenged by excessive utilization of imaging.

The relationship between utilization of imaging and its *costs* is certainly also ethically relevant, as radiology is a relatively costly high-technology discipline. If imaging is used excessively, the benefit to society may be compromised because of changes in the balance between outcome and costs. In the United States, there is a strong focus on expenses for use of imaging, as today it stands out as "... one of the highest cost items in a health plan's medical budget and also one of the fastest growing" [14]. Under Medicare's physician fee schedule, the volume and intensity of services per beneficiary of no other service increased as rapidly as the volume of diagnostic imaging, from 1999 to 2004: it increased by 62%, which was twice as much as the increase in the sum of all physician services [23]. Without claiming that the same trend is present in Norway, our expenses have also been increasing: from 1997 to 2002 public reimbursement expenses approximately doubled [24]. In 2003, the total cost of diagnostic radiology and laboratory services combined was NOK 5.7 billion, which constituted approximately 4% of the total running health expenses [25]. The hospital reform was implemented the previous year (2002). This reform gave the Regional Health Authorities (RHFs) increased responsibility for financing and regulating these services, i.e. enabling them to decrease the overall cost of ambulant radiology services [26]. However, this did not seem to occur, because the prices paid by RHFs to the radiological institutes (possible through increased block grants and regulated in contracts between the RHF and each institute) increased corresponding to the reduced refund rates from the National Insurance Administration (RTV Rikstrygdeverket) [26].

New technology tends to place additional pressure on health care resources, i.e. new diagnostic tests [3] and methods contribute to increase the gap between what is medically possible and what is economically and ethically justifiable [27]. This makes rationing and prioritization both more needed and more difficult in physicians' clinical practice. However, the introduction of new imaging technologies can also bring cost savings, by replacing invasive methods, such as exploratory surgery, with less invasive and more cost effective methods [5].

Basic principles of justice and prioritization require that cost-effectiveness is taken into account [27], though the question whether limited health care resource could have been utilized better elsewhere, e.g. in other medical sectors, becomes more pressing when services are used excessively. The question of distributive justice may arise, because excessive utilization in some populations may increase rationing in others. Picano et al. warn that excessive utilization "seriously endanger access to the benefit of sophisticated testing for those who are in real need" [14]. When addressing the question of distributive justice in cases of equal medical needs, we assume that populations receiving most services will benefit most. This is not necessarily always true, e.g. Fisher et al. found that residents of high-spending regions received more care (including frequent tests), but did not find that this led to "improved survival, slower decline in functional status, or improved satisfaction with care" [28].

[3] The newer technologies are generally more costly e.g. MRI scans now cost NOK 2000 (plus extras for contrast media, addition series etc.), roughly three times the price of plain x-rays.

Finally, questions about how the service is utilized are important to the professionals providing the service, and excessive utilization represents both a practical and a moral challenge [29,30]. To perform unnecessary examinations is reported to upset radiographers morally [31]. Excessive testing may be distressing to radiologists if the quality of the services is compromised. Quality in radiology is said to presuppose that radiologists take professional responsibility for the "selection of subjects for imaging, the determination of optimal imaging approaches, tailoring imaging interpretations to specific clinical scenarios, and ensuring appropriate management on the basis of imaging results" [32]. The responsibility to differentiate between adequate and exaggerated imaging and to act as gatekeeper is important to maintain professional autonomy and self respect [33]. This is morally grounded in the duty to reduce harm (including to minimize radiation exposure), provide quality care, and avoid futility.

Major concerns about over-utilization and the involved risks, costs and possible compromised quality, are the main reasons why (also from an ethical perspective) it is important to survey utilization, and to address the issue of the utility of diagnostic imaging. Research in the field has been rather sparse, though the results of such research should interest policy makers, radiation protection authorities, professionals and patients.

1.3 Aims of the study

The overall aim of this dissertation is to increase our understanding of the utilization and utility of diagnostic imaging, which may be valuable in management of the services. To obtain a better understanding, I will pursue five steps. The first four steps are dealt with in the articles. These articles present different aspects of the actual utilization of imaging, and as perceived by radiologists. The fifth step is to analyse the utility of service in the light of the empirical research, which will constitute the normative discussion in the dissertation. The five steps are as follows:

I. To investigate changes in radiological examination frequencies in Norway, more precisely:

a) What are the changes in overall examination frequency?
b) Do newer technologies (CT and MRI) tend to replace or supplement conventional radiography?

c) What changes in collective effective dose [4] follow from changes in examination frequency?

II. To study variation in the use of X-ray, computed tomography, magnetic resonance imaging and ultrasound between Norwegian counties, including the questions:

a) Does low use of one modality for examination of specific organs (locations) tend to be substituted by correspondingly high use of other modalities?
b) Is geographical variation in examination rates influenced by contributions from private institutions, different aspects of accessibility and socioeconomic factors?

III. To obtain radiologists' views on factors influencing the use of radiological investigations:

a) What do they perceive as the main causes [5] of increasing investigation volume?
b) To what extent do unnecessary investigations, for different reasons, occur at their own workplace?
c) Do perceptions of a) and b) differ between subgroups of radiologists?

IV. To investigate radiologists' responses to inadequate imaging referrals:

a) How do radiologists act when confronted with ambiguous indications or inappropriate examination choices in the referral forms?
b) What factors affect radiologists' decisions to prevent or not to prevent an examination of doubtful usefulness from being performed?
c) Do such actions (a) and factors (b) differ between qualified specialists versus registrars, and between radiologists in public hospitals versus in private institutes?

V. To discuss utilization of diagnostic imaging from a utilitarian perspective, addressing two main questions:

a) What is the relationship between increasing utilization and utility of the services?
b) What is the utility of different norms and measures (existing and suggested) to influence or manage utilization?

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[4] The *collective effective dose* (CED) is the sum of the individual radiation doses in a group of people. More precisely, CED is the sum of the mean *effective dose* to patients from a particular examination multiplied by the corresponding number of examinations of that type performed each year, measured in man-sievert. The *effective dose* from an X-ray examination is calculated by taking the absorbed dose to selected organs and multiplying with tissue weighting factors. The resulting sum quantity is used to express the detriment to the whole body, i.e. the risk of late effects from exposures of ionizing radiation.

[5] The concept *cause* is not used here in a strict scientific manner, but more as in everyday language. The term refers to factors, conditions, circumstances etc. that can possibly influence the use of imaging.

1.4 Previous empirical research on the utilization of imaging

Research so far regarding utilization and the factors that influence use is outlined in this section to illuminate the need for our surveys. Some relevant features of the Norwegian health care system are then described.

1.4.1 Surveying utilization of radiological examinations

The frequency of radiological examinations and associated radiation doses has been surveyed in developed countries for some decades now. The general trends are substantial increases in utilization of high-technology and high-cost diagnostic imaging [34-39]. Some findings indicate an escalating growth rate, e.g. the utilization of CT in the United States [40] and in Denmark [41] as shown in Figures 1 and 2. Another example is the remarkable increase in frequency of CT examinations in paediatric emergency departments reported from the United States, where e.g. cervical spine CT and chest CT increased approximately five-fold from 2000 to 2006 [42].

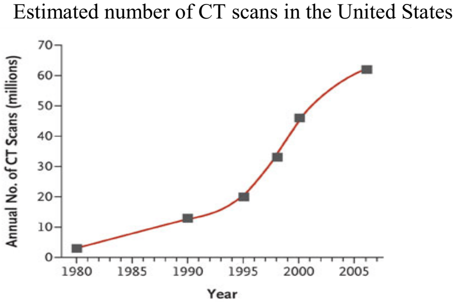

Figure 1: Estimated total number of CT scans performed in the United States [40].

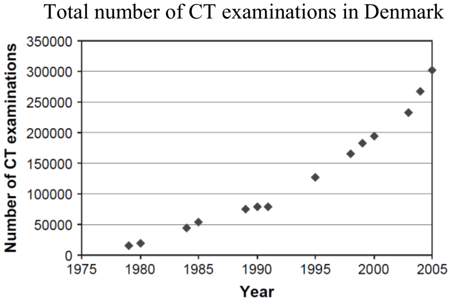

Figure 2: Reported total number of CT examinations from 1979 to 2005 performed in Denmark [41].

To a large extent, examination frequency has been investigated for the purposes of estimating radiation doses to the population, hence examinations not based on ionizing radiation (MRI and ultrasound) are excluded. For example, from the 1980s, UNSCEAR (the United Nations Scientific Committee on the Effects of Atomic Radiation) has provided estimates [6] of the worldwide frequency of exposure to radiation and of radiation doses [43]. Its latest report shows huge differences between the utilization of imaging in countries with the highest levels

[6] The UNSCEAR estimates are based on extrapolations of reported figures from some countries [43].

of health care and those with lower levels, and a distinct increase in examination frequency the last 10-15 years in the former. The total increase in frequency has caused a doubling of the average per capita effective dose worldwide (0.61 mSv), though the effective dose in the countries with the highest levels of health care has trebled (1.87 mSv) according to the latest estimates [43].

However, there are also huge differences in utilization of imaging between countries with the highest levels of health care, according to UNSCEAR's report from 2000 [44]. Utilization was reported to be highest in Japan, with an estimated annual total of 1477 examinations per 1000 population, which was three times as high as in Taiwan, Denmark, Greece, Romania, and the United Kingdom. Among other countries with high use, we find the United States, the Russian Federation and Germany, while Romania and South Africa had low use of imaging [44]. There are also substantial differences between the European countries (see Figure 3, where the light bars are the number of x-ray examinations per 1000 inhabitants) [45].

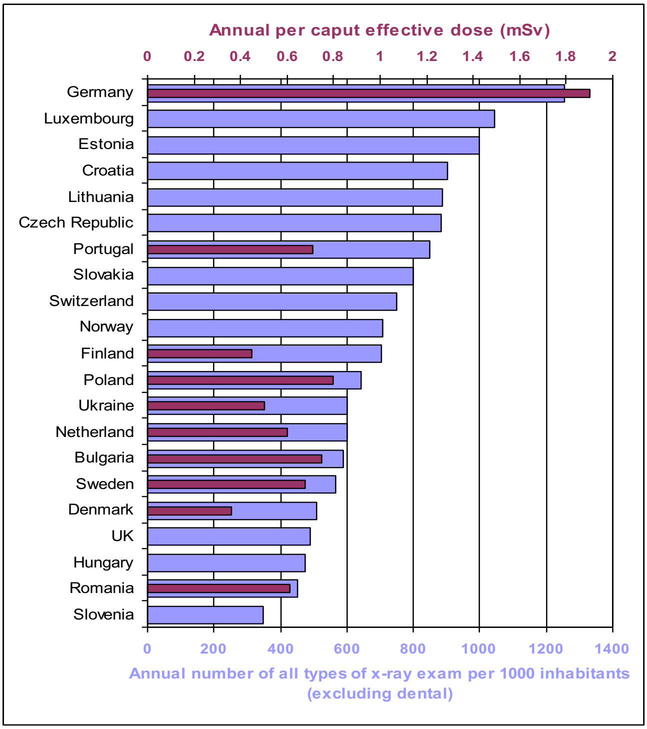

Figure 3: Differences in annual rates of all types of x-ray examinations (the broad, light bars) and per capita effective dose (the narrow, dark bars) in Europe [45].

Geographical or small area variation in imaging has perhaps been most studied and documented in the United States [46-48], though also in Europe between [49] and within [37,50] countries. The more alike the compared areas are regarding health care resources and policy, and systems for referrals and reimbursement, the less expected and more challenging geographical variation becomes. Hence, it is surprising when MRI rates varied by a factor of 2.5 and CT by a factor of 1.5 between regions in Sweden [37]. The huge variations in utilization of imaging between and within countries and regions cannot be explained by differences in disease prevalence. Hence, underuse and/or overuse of imaging must exist to a large extent.

To be able to describe how utilization of imaging develops, we need detailed data on utilization of the different types of examination. Among the open questions are: For which kinds of examination has there been an increase or a decrease in utilization? How great have changes in utilization been? What is the effect of changes in utilization pattern on population doses? If use of imaging varies geographically, which kinds of examination vary the most? Have newer technologies replaced or substituted traditional conventional technologies?

Surveying time trends and geographical variation in use of imaging may indicate which factors influence utilization, e.g. the impact of availability. However, the question has to be investigated further in order to get an overview, and to identify the core influencing factors.

1.4.2 Exploring factors that influence utilization of diagnostic imaging

Investigating factors that influence utilization of imaging is an important element of the work to increase the appropriateness of examinations. This requires knowledge of the relative impact of the factors combined with normative assessments, discussions and evaluations of their justifiability. But first the factors must be identified.

I have already indicated that progress of the technology has been proposed as a major cause of the rapidly increasing use of imaging [3], and that supply and availability of the technology are considered to be important factors that influence utilization [51]. The introduction to Article III of this dissertation presents a series of other factors reported in previous studies. Some important factors are the payment system, an aging population, patients' expectations and pressure, and physicians who are uncomfortable with uncertainty.

Causal factors are often mentioned in empirical studies of utilization and appropriateness of referrals, though merely as suggested explanations of the findings in the discussion. If possible causal factors are the scope of the study (i.e. measures of associations), one or a few factors are often focussed on. When more factors are included, the studies are most often qualitative interviews with a few general practitioners [52,53] or patients [54]. This gives very useful information about the factors that are in play when decisions about referrals are made. However, this methodological approach does not allow comparison and ranking of the different factors. Consequently, there is a lack of knowledge about the relative importance of the spectrum of potential factors that influence the utilization of imaging.

Radiologists can contribute to fill this void. They possess valuable experience and knowledge for assessing the relative impact of factors that influence the utilization of diagnostic imaging. They have gained expertise by handling a multitude of referrals and by interactions with a range of referring clinicians and patients. But the topic has hardly ever been studied from their perspective, i.e. the service provider perspective. Equally absent is knowledge about how radiologists influence the utilization of imaging and their reasoning when they receive a referral. By contrast, the referring physician's reasoning when deciding to refer a patient to radiological investigation has been fairly well explored and documented.

1.4.3 A brief description of the Norwegian context

The Norwegian health care system is traditionally characterized by equality, solidarity and moderation [55]. This may be the reason why work with prioritization of health resources started early in Norway [7]. Patients should be treated equally, irrespective of their financial or social status, at the lowest effective level of care. The gatekeeper role of physicians "reflects economic responsibility as well as some hesitation in the use of extensive diagnostic and therapeutic procedures" [55]. Norwegian medicine has not been characterized by eagerness in interventions or on the implementation of new technology. This may be due to strong governmental control, traditional economic moderation and a low degree of market

[7] The first work on prioritization was a reported by the Lønning I Committee in 1987 [27], which proposed a five-level model for prioritization with seriousness and effectiveness as basic assessment criteria (the criteria of cost-effectiveness was added later). A new council (the Norwegian Council for Quality Improvement and Priority Setting in Health Care) was established in 1997 to facilitate continuous work in this field, but there are still many challenges regarding implementation in clinical practice [56].

adjustment in the health services [55]. Health care is based on a tax finance system (through the National Insurance Scheme), which also covers the vast majority of radiology services, including private radiology services (institutes run by radiologists). For these reasons one would expect moderate utilization and moderate regional variation in use of imaging services in Norway.

On the other hand, there are some reasons why this expectation may not be realistic. Traditional ideals are currently under pressure, our society is becoming more individualistic and market oriented (like other countries) and health care services are gradually becoming more like a service enterprise emphasizing supply and demand issues [55]. For instance, we now have guarantees against long waiting time for access to services, and free choice of hospital. Health services have high political priority and people have high expectations of the services [55], possibly due to the wealth of the country. A survey in 1993 showed an overall increase in examination frequency of 10% over a decade, while the use of CT doubled every fifth year [57]. Few investigations of geographic variation have been done, and differences in rates of radiology use in urban and rural areas in Norway observed in an earlier study were not quantified [58].

1.5 Normative debates of imaging utilization

I have explained above (Section 1.2) how studies of utilization of imaging are interesting from an ethical point of view due to concerns about overuse. These concerns are mainly related to consequences (compromised utility and quality of services, imbalance between benefits, risks and costs, distributive injustice etc.). The likelihood of these consequences occurring is an important part of discussions about the utilization of imaging among professionals, along with other empirical questions. In these debates there are also disagreements over conceptual questions, like 'what is a useful examination?' I will return to these issues in Sections 1.7 and 1.8. Here I will elaborate on some recurring issues in the normative debates:

a) Disagreements about the magnitude and justifiability of factors influencing utilization. Opinions about these matters constitute central elements in the argumentation for promoting or restricting the use of imaging.

b) Disagreements about who should have responsibility for how the services are utilized, and what measures should be taken to manage utilization, if this is regarded as necessary.

Within the ethics of radiation protection (a new field of applied ethics), the questions of "how and by whom the various decisions that influence exposures should be made" are among the most important [59].

1.5.1 Should utilization of imaging be restricted or promoted?

In the wake of empirical reports on increase or variation in utilization of radiological services, debates arise about whether this is beneficial. These debates have typically been rather polarized and somewhat simplified, one side arguing for a more restrictive approach, and the other side for a more permissive practice. These fractions can also be identified in the debate in Norway that took place in 2000 after it was reported that public expenditure for private laboratories and radiological institutes had increased by 30% in one year. [8]

Heilo et al. [60] represent the restrictive position. They highlighted a number of factors causing the reported increase that they judge to be unjustifiable: demanding ("healthy") patients, compliant clinicians (fearing liability), advertising (for expensive examinations), and lack of critical assessment of referrals at the radiological institutions for economic and competition reasons (by both the individual radiologists and the institutions) [60]. They believe that compliance with examination requests increases, because institutions fear losing "their share of the market" [60]. Heilo et al. apparently reckon that these factors are influential, since they end up considering that overuse and inappropriate use of radiological examinations must be substantial. Another restrictive voice (a community health physician) in this debate elaborates on supplier induced demand, arguing that easy access and advertising (like for drop-in CT) that meets "a large reservoir of "needs" in the population" is a significant and morally unjustifiable explanation for increased utilization of imaging [33].

The permissive debaters emphasise other explanatory factors for increased utilization, which they believe are justifiable: technological developments, the increasing importance of imaging

[8] I will draw much on this discussion, because this is a Norwegian project and access to information is good. Such debates may not be likely candidates for publishing in international journals. The temperature of this debate indicates that radiologists find the issue of utilization of services important. The debate is also a dispute between radiologists employed in hospitals and in radiological institutes, which is of limited interest here.

in early and presymptomatic stages of disease (requires a low threshold for access), and increased patients' rights to participate in the decision-making process [61]. Behind the role of technology there are two arguments: that radiology can resolve more clinical problems, and that new modalities are harmless [62]. It is argued that a number of investigation methods have been replaced by new (and more expensive) technology [63]. The safety and feasibility of services should both a) lower the threshold for referring and b) shift the setting to more outpatient services [63]. On this background it is argued that the increased use of imaging should not surprise anybody (colleagues, payers or politicians), but should rather be an expected and accepted development [61]. It is claimed that statements about overuse of imaging in Norway lack documentation [62].

The value of early access is fundamental in the arguments of proponents for increased use of individually requested screenings, emphasizing the patient's right to decide [64]. But it is also stated that primary care physicians more frequently use imaging to support their decisions about whether to make additional referrals to other specialists (neurologist, orthopaedist etc.), which is justifiable for reasons of diagnostic certainty, efficiency and cost-effectiveness [65].

The list of justifiable and unjustifiable causal factors that have been mentioned is not meant to be an exhaustive list. These factors represent some common elements in the discussions about imaging utilization, both in Norway and internationally. The Norwegian debate is representative regarding causal factors, apart from the absence of two factors that have been greatly emphasized in other contexts, particularly in the United States: defensive medicine and self-referrals [15,66,67]. In addition, patient autonomy has been given more emphasis in other contexts [64,68]. The following statement illustrates the two positions:

> "Advocates for this phenomenal growth claim that they are only addressing consumer demand, satisfying referring physicians demands and delivering superior patient care. Opponents, on the other hand, particularly the third party payers, point to an unsustainable burden on their cost structure. Some also suggest there is an inherent conflict of interest within hospital organizations, opining that it is in their interest to scan as many patients as possible, in the hope of maximizing profit."[69].

In the professional journals, there is a clear majority of articles in which a restrictive position is argued for. This is not surprising, since, in these articles, it is argued that practice should be changed, because of the growth in investigation volume. The motivation to argue for "business as usual" may not be equally strong.

1.5.2 Who are responsible for how imaging is utilized and what should they do?

It is commonly recognised that utilization of imaging should be a shared responsibility. The disagreement concerns the relative weighting between the involved parties. The permissive versus the restrictive dichotomy also makes sense in sorting out the positions in the debate about responsibility and what should be done.

A permissive position implicitly ascribes responsibility for utilization of imaging to the patient. As the patients' influence is regarded as a good thing, representing a democratization process, the appropriate professional actions would be to respect and pay more attention to patients' wishes [61]. More explicitly, the power to make the decision is assigned to the referring physician, acting on behalf of the patient. The specific knowledge of radiologists is regarded as insufficient ground for assessment of the patients' need for examinations [62]. The referring physician has insight in the total situation of the patient, which should have priority over the too narrow perspective of radiologists [70]. For example, only the referring physician may know that a patient's fear of malignant disease is destroying his/her social life, which is regarded as a justifiable reason for a reassuring examination [70]. The radiologist's role is not to override the referring physicians' assessment, but to inform and give advice about the use of the service [70]. It follows that measures to improve utilization can only aim to make sure that access to services is sufficient.

From a restrictive point of view, the influence of patient demand for imaging services should reinforce the professionals' gate-keeping responsibilities to try to "curb an emergent security hysteria in the population" [33]. Patients are rarely ascribed any responsibility. However, as part of a restrictive strategy, it is suggested that patients should be better informed about "the risks, benefits, and uncertainties of specific interventions" [20]. It is also suggested that patients should, explicitly and transparently, sign an informed consent form for each radiological (high dose) examination [71,72]. Correspondingly, doctors should be required to have a "radiological prescribing licence" [71]. These remedies are supposed to combat ignorance about appropriate use and radiation doses and thereby reduce the pressure for, and prescriptions of, redundant examinations. Again, the referring physicians are left with the greatest burden of responsibility, and as with the permissive argumentation, the measures are still to inform physicians and to guide their decisions. The means may however differ, emphasizing radiological consultations, guidelines, preauthorization etc. It is quite common for radiologists to argue that they should educate referring physicians about the appropriate use of examinations [15,66,73].

Voices in the radiologist environment argue that radiologists should bear more responsibility for utilization of imaging [30,32,60,69,74-80], emphasizing their independent responsibility for radiation protection, reduction of waste and limitation of costs. Heilo et al. call upon radiologists to be more actively and visibly engaged in decisions about examinations, rooted in professional knowledge, self-esteem and autonomy [60]. Radiologists "have the greatest expertise regarding the utility of different imaging techniques for depicting disease" [35], and the right and the duty to intervene when aware of unnecessary testing [81]. A few quotes follow to illuminate how this responsibility is perceived:

- " …the radiologist has the appropriate professional training to be the gate keeper and guardian of the patients' interests in the face of financial and clinical pressures to act otherwise" [82].
- "As the experts in diagnostic imaging, radiologists have special obligations. It is our ethical responsibility to protect our patients. […] We must recognize that it is our obligation to raise questions when receiving requests to perform imaging of questionable value" [75].
- "... the radiologists' role is to provide unbiased opinions about the most effective and least expensive modality, including recommending no test where applicable" [83].
- "…radiologists need to move more aggressively into the future, assuming more responsibility in clinical care. Radiologists can maximize their contribution to patient management as active participants in the process of medical care delivery" [84].

In summary, there are debates about how current utilization of imaging should be conceived, whether use should be promoted or restricted, and why. Likely consequences are often mentioned, but whether (excessive) imaging is mainly considered useful, futile or harmful are rarely discussed thoroughly. Despite different opinions about appropriate measures by the involved parties, most suggested strategies somehow require involvement by the radiologists. In any case, the usefulness of these strategies needs to be further investigated.

1.6 Utility and utilitarianism as the normative perspective

Utility and utilitarianism have been chosen as the perspective for the normative discussions in this study. A comprehensive account of this theory is beyond the scope of this thesis, but I will describe some features of utilitarianism and some objections/criticism, emphasizing those relevant for the later discussion. I will end this section by explaining why utility and utilitarianism provide a relevant perspective for this dissertation and the role of empirical research in the (current) normative analysis.

1.6.1 What is utilitarianism?

Utilitarianism is said to be the paradigm case of consequentialism which "is the view that normative properties depend only on consequences" [85]. The core of utilitarianism can be described in this way: "Utilitarianism assesses acts and/or character traits, practices, and institutions solely in terms of overall net benefit, which is often referred to as well-being or welfare" [86]. Utilitarianism seems compellingly straightforward, being based on the single principle of maximizing utility. An action is right if it is expected to generate a higher or equal amount of welfare than relevant alternatives – all involved parties considered [87]. Relevant alternatives include both alternative actions, and abstentions, because failing "to promote a person's well-being is morally equivalent to harming that person" [88, p. 125]. Given that 'all involved parties' must be considered, a single person should not be given priority at the sacrifice of others – an egalitarian thought where each person counts for one [88, p. 117]. The principle of maximizing the good and minimizing the harm also "seems to be one of the main elements of our conception of practical rationality" [89, p. 1].

Besides the principle of maximizing good consequences and impartiality, there are additional distinct claims about moral rightness accepted in classic utilitarianism, which makes the theory more complex than it might appear. Sinnott-Armstrong [85] lists a number of these claims, for instance that moral rightness depends on *actual consequences* (not foreseeable or likely), on *the act itself* (not the agent's motives or a rule), on *agent-neutrality* (not dependent on whether the consequences are evaluated from the agent's or the observer's perspective), and that the value of consequences depends only on the *pleasures* and *pains* it brings about. The acceptance of such a variety of (logically independent) claims "makes classic utilitarianism subject to attack from many angles" [ibid], and very few philosophers today agree entirely with the claims of classic utilitarianism (especially the claim of a hedonistic value theory) [90]. More recent theories following the classical *act utilitarianism*, such as *rule utilitarianism* and *preference utilitarianism,* differ regarding these claims. In the following section I will bring up three questions where these theories, and also non-utilitarian consequentialism, have alternative answers and arguments to the question about: what goods to promote (values theory), how the good can be promoted (morally defensible conduct), and implementation of utilitarian thinking in health care.

1.6.2 Utilitarianism and values

Even though the general view in utilitarianism is that "the morally right action is that action that produces the most good" [90], there are differences in how good, benefit or welfare is conceived or defined. To classical utilitarians welfare is purely a matter of pleasure and pain [86]. This hedonistic claim, that pleasure is the only intrinsic good and pain the only intrinsic bad, was criticized already at the time of Bentham and Mill [85]. [9] The main problem in this view, is that "many (if not all) people care very strongly about things other than their own pleasures and pains" [86], e.g. the values of truth, autonomy, freedom, friendship, justice etc. Such things "can be important as means to pleasures and to the avoidance of pain. But many people care very strongly about things over and beyond their hedonistic instrumental value" [86]. Hence, the act utilitarian reply that we estimate these values because they promote pleasure is rejected [91]. Some critics also argue that "not *all* pleasures are valuable, since, for example, there is no value in the pleasures of a sadist while whipping a victim" [85].

Preference utilitarianism uses satisfaction of desires or preferences as a proxy for utility. The difficulties of defining which goods to promote is avoided by allowing "each individual to define for himself what pleasure and pain is" [91]. Preference may or may not include intrinsic values beyond pleasure and avoidance of pain [91], but what we usually prefer is not the sensation of pleasure but rather "a state of affairs, such as having a friend or accomplishing a goal" [85]. Still, this position is confronted with problems with preferences that are antisocial, irrational (e.g. distorted by misinformation), and trivial [91]. Another objection against preference utilitarianism is that it is unfair to prioritize individuals because of their strong preferences, also because our expectations are sensitive to whether or not we are used to getting our preferences satisfied [91].

[9] As opposed to Bentham, Mill "distinguished between higher and lower qualities of pleasures according to the preferences of people who have experienced both kinds", i.e. a qualitative hedonism [85].

A main reason for consequentialists not to call themselves utilitarians [10] is that they deny that the welfare of individuals alone determines the value of consequences. Rather, they argue for pluralism about intrinsic values, where the main ones are justice, fairness and equality. That utilitarianism "gives no direct weight to considerations of justice or fairness in the distribution of goods" is one of the most influential objections to utilitarianism, presented by Rawls [89].[11] Because utilitarianism is not concerned with welfare levels, but only welfare differences [91], distribution of welfare between individuals is neglected. Therefore utilitarianism will recommend channeling resources to those already well provided, at the expense of those suffering from small resources, if this maximizes welfare. A utilitarian reply is that radically inegalitarian distribution of resources will in fact almost never produce the greatest utility [89]. One reason for this is that "welfare changes depends on welfare level" according to *the law of diminishing marginal utility* [91], which means that the utility a person gains from a certain unit of a good or service falls as the units of the good or services increases [86,91]. In general, material resources have diminishing marginal utility, [12] as illustrated in Figure 4.

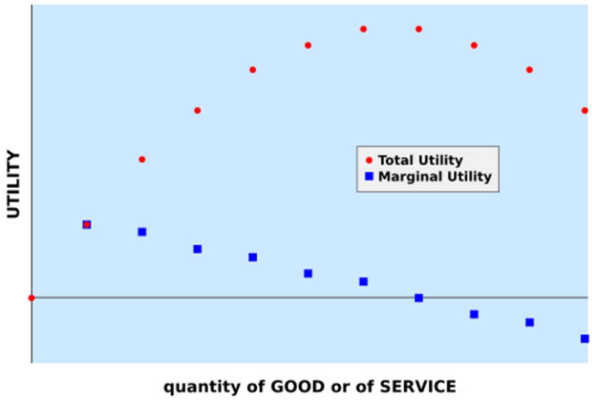

Figure 4: "Diminishing marginal utility, given quantification" [92].

[10] The use of these concepts is not uniform, as non-welfarist views can also be called utilitarian [85], and the concept nonutilitarian consequentialist can mean "not purely utilitarian" rather than "completely unutilitarian" [86].
[11] According to Scheffler, the other two particularly influential objections are that maximization of utility may require people to do something horrible, and that the theory is excessively demanding "because it seems to require that one neglect or abandon one's own pursuits whenever one could produce even slightly more good in some other way" [89, p. 3]. Such results conflict with our moral intuition. However, these objections are less relevant in the context of utilization of diagnostic imaging.
[12] The exception from the law of diminishing marginal utility is mainly cases where "an additional unit of material resource pushes someone over some important threshold" [86]. The arguments against that the law of diminishing marginal utility provides utilitarianism with distributive justice include examples where it is not true, or too demanding [91]. For instance: "an additional unit of education given to a child who is already well-off may lead to a larger net present value of utility than if the educational unit were given to a child who is already in a bad position, but simply shows little improvement from education" [91].

The law of diminishing marginal utility tells us that overall benefits are in fact best promoted by allocating resources to those worse off, i.e. supporting egalitarian justice. However, critics may not be persuaded, since utilitarianism would still set aside distributive justice if and whenever this does not promote maximum utility [89]. The two ways that utilitarians can accommodate distributive concerns is to give "extra weight to the interests of those who are worst off … [and] by treating distributive equality as good itself", when determining the overall outcome [89, p. 6]. As mentioned above, utilitarianism requires that the interests of all parties are taken into account without any specially favoured or disfavoured parties. Hence, "[m]any think that a purely utilitarian formula has sufficiently egalitarian implications" [86]. Besides, a rule utilitarian argument is that "justice and fairness are constituted by conformity with a certain set of justified social practices, and that what justifies these practices is that they generally promote overall welfare and equality" [86].

1.6.3 Utilitarianism and morally defensible conduct

Utilitarian theories also differ in how they see the relationship between promotion of welfare and right conduct, i.e. how utility can be achieved. [13] According to *act utilitarianism,* the alternative actions in each particular situation must be considered in an unbiased manner. This requires knowledge of the particulars of the case (including probabilities) and sensitivity to the impact of the decision to those involved [87]. It is crucial that we gather empirical evidence for "what is likely to happen to people, now and in the future, as a result of the various alternative actions" [88, p. 123]. As we may lack detailed information and can never be absolutely sure of the likely consequences in the *particular* case, we must base our decision on the best available information [ibid]. The procedure is as follows:

> "We should understand what all the relevant available alternatives are, gather the best available evidence on what the consequences of each of these are and, how likely each of these consequences are, and then we can make a decision based on this and of what, on the balance of probabilities on the available evidence, is likely to have the best outcome [88, p. 125].

This quote says that it is the expected or predictable consequences that should be considered, as opposed to the factual consequences. As already indicated, this challenges classic utilitarianism, as the moral rightness depends on the expected (foreseen, foreseeable, intended or likely) consequences, and not on the actual consequences [85]. The reason why it is less

[13] Variants of utilitarianism also have different "thesis about the conditions under which moral sanctions such as blame, guilt and praise are appropriate" [86], but this is of less relevance to this dissertation.

common to claim that the right action is the one that actually does maximize utility (objective utilitarianism) is that the agent then can “become accountable for random events she is unable to predict” [91]. It seems also reasonable only to take into account the predictable consequences that are foreseeable by the agent, since complete information about all predictable consequences is often unrealistic [91].

According to Hooker [86], the act-consequentialist decision procedure can be counter-productive for four reasons: a) the agent’s lack of knowledge about the consequences of various acts, b) the high costs of obtaining such knowledge, c) the agent makes mistakes in the calculation of consequences and d) that people (who are naturally biased towards themselves and their nearest and dearest) can break social rules (like keeping promises, lying etc.) if they become convinced that this would maximize overall good. One aspect of lack of knowledge is the difficulties of assessing others’ welfare, e.g. our perception of poor consequences can be distorted by defence mechanisms like denial or adaptation [91]. Mistakes in calculation of consequences are particularly likely when the “the agent's natural biases intrude, or when the calculations are complex, or when they have to be made in a hurry” [86]. Even though act utilitarians do not give intrinsic value to social rules, they can argue that it is critical to preserve them because of the devastating consequences if everyone violates them [91].

Sinnott-Armstrong [85] points out that extensive calculation of utility (by each agent, of all consequences of each act for every person) as a *decision procedure* is a misinterpretation. This is neither possible nor warrantable, because of the just-mentioned disutility of such calculations. Rather, most utilitarians and consequentialists claim that overall utility is the *criterion* of what is morally right and ought to be done [ibid]. “A criterion of the right can be useful at a higher level by helping us choose among available decision procedures and refine our decision procedures as circumstances change and we gain more experience and knowledge” [85]. Even if we cannot know or predict all consequences before acting, we can have strong reasons to think that a certain act reduces or increases utility, and accordingly think that it is morally wrong or right [ibid]. Similarity it is argued that it is impossible to define an interpersonal absolute unit to measure and compare utility (the so-called util), but people often make interpersonal comparisons of utility good enough for rough assessments [91].

To avoid the disutility of calculating consequences on a case-by-case basis, rules for decision-making are needed, but in act utilitarianism such rules are not mandatory as in rule utilitarianism [91].

Rule utilitarianism is a theory in which an act is right if it accords with a rule, which, if generally followed, has at least as good consequences as alternative rules [87]. 'Rule' is not to be understood here as a very specific instruction constructed on the basis of the particular situation, i.e. as universalization of certain actions [ibid]. Examples of endorsed rules are: "Don't harm innocent others", "Don't steal or vandalize others' property", "Don't break your promises", "Don't lie", "Pay special attention to the needs of your family and friends", "Do good for others generally" [86]. Central questions for a rule-utilitarian are 'what would be the consequences if everyone violated such rules'?, and 'what would be the consequences if a rule was generally accepted that forbade one to act honestly, to do good for others and so forth? [85]. The point is that a society where rules like "Don't lie" etc. are widely accepted "would have more good in it than one lacking such rules" [86].

> The "basic idea behind rule utilitarianism is not that it will provide the maximum utility in each scenario but rather that over time and all scenarios, conformity to the rule will result in greater utility than will actions that are based upon case-by-case projection of what to do" [91].

Also the expected good from a set of rules could in principle be calculated, [14] but such calculations would often be impressionistic [86]. "Nevertheless, we can reasonably hope to make at least some informed judgements about the likely consequences of alternative possible rules. And we could be guided by such judgements" [86]. If two rules are judged equal in terms of expected good, we should choose the one that is closest to conventional morality, because social changes often have unexpected (and negative) consequences. It is also important in the judgment not to ignore the "transition" costs of getting rules accepted [86].

The acceptance of rules can require that they become publicly known or that they are built into institutions, while others are built into our individual conscience. By referring to generally accepted rules some hold that this theory better reflects common moral reasoning [85].

[14] The procedure of calculating the expected good of accepting a set of rules is to multiply the values and disvalues by the probability of each rule, and then add the products of these multiplications together [86].

One objection to rule utilitarianism is that it collapses into practical equivalence with act utilitarianism. The argument goes like this: In cases where compliance with a simple rule like "don't lie" would produce less good than non-compliance with the rule, "rule-consequentialism seems driven to admit that compliance with the rule "don't lie except in cases like this" is better" [86]. In other words, rule-consequentialism could end up favouring infinitely amended rules to not miss out any cases where a simpler rule would not produce the greatest expected good [86]. The reply is that it is not the expected good of *complying* with rules that decides the ranking of rule systems, but rather the expected good of their *acceptance*. A "widespread awareness of a ready willingness to incorporate an indefinite number of exceptions to rules ... could undermine people's assurance that others will behave in certain ways (such as keeping promises and avoiding stealing)" [86]. To provide certainty or foresightedness about how others will behave is certainly very useful in a society. The relative costs of getting widespread acceptance would also be lower with fewer and simpler codes of rules than the demanding complicated ones [86].

Another objection to rule utilitarianism is that it is incoherent, as it holds that an act that maximizes the good still can be morally wrong [86]. The reply to this is that "neither the rule-consequentialist agent nor the theory itself contains an overarching commitment to maximize the good" [86]. [15]

Yet another approach is to combine act and rule utilitarianism; so called *two-level-utilitarianism*. In ordinary conflict-free situations one should follow rules (here: prima facie-norms) which have proven to produce good consequences, without considering alternative actions [87]. In conflict situations, on the other hand, we should put rules aside and ask what action would maximize utility in the situation at hand. Richard Hare explains the content and purpose of the second level in this way:

> "the second (level 2) consists in the criticism, and possibly the modification, of these general principles in the light of their effect in particular cases, actual and imagined. The purpose of this second, reflective kind of thinking is to select those general principles for use in the first kind of thinking which will lead to the nearest approximation, if generally accepted and inculcated, to the results that would be achieved if we had the time and the information and the freedom from self-deception to make possible the practice of level-2 thinking in every single case." [93].

[15] The theory only claims "(1) that rules are to be selected solely in terms of their consequences and (2) that these rules determine which kinds of acts are morally wrong ... [and the agent] would be morally motivated to do as rule-consequentialism prescribes" [86].

1.6.4 Utilitarianism and health care

Utilitarianism has not only been very influential within moral philosophy, but also within social policy [90]. Within medical and public health policy today "utilitarianism appears to be the dominant view of justice" [94]. [16] The consequentialist orientation, in general, in public health is that it seeks to promote good, and avoid bad, health outcomes, and "this outcome-orientation is viewed as the moral justification and foundation of public health" [95]. One reason for the strengthened position of utility considerations and utilitarianism in health care policy is that it fits well with current demand for evidence-based medicine and the demand for rationing of limited health care resources [88].

However, there may be good reasons why the role of utilitarianism is somewhat controversial in modern medical ethics despite its conspicuous position [96]. Objections to the theories in general are also relevant in a health context. The attempt to solve the difficulties of defining a unit for utility by using health as a proxy is problematic because utility captures more than health, e.g. social relationship and wealth [91]. Welfare or preferences are by no means fully equivalent with health and small health improvements may not be chosen because more utility can be gained outside the health care service [91]. Hence, maximization of utility does not necessarily imply maximization of health.

Nevertheless, measures like quality adjusted life years (QALYs) have been introduced in health care policy, and this construction entails the use of utilitarian theory [94]. QALYs were never meant to be a comprehensive measure of quality of life, but to measure "those of its dimensions which are of primary importance in health care" [97]. In the QALY system, the 'worth' of a year of perfect health is scaled to one, and a year of less than perfect health less than one [7]. The purpose of QALYs is to be able to compare cost-effectiveness (CEA) or cost-utility (CUA) [17] across different technologies and patient groups [7].

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[16] Other prominent positions on just allocation of health care resources (like the position of Norman Daniels) invokes John Rawls's principles of "fair equality of opportunity" and the "difference principle" [94]. The first principle requires "a liberal democratic political regime to assure that its citizens' basic needs for primary goods are met and that citizens have the means to make effective use of their liberties and opportunities… [and the] second principle regulates the basic institutions of a just state so as to assure citizens fair equality of opportunity" [94]. More precisely the "difference principle" requires that "governmental policies that distribute goods between citizens must be designed to rectify inequality by first advancing the interests of those who are otherwise less well off than their fellow citizens" [ibid].

[17] Cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) are methods to compare the benefits and costs of different alternative actions. They are both similar to cost-benefit analysis except that benefits are not measured in monetary terms [7]. In CEA, benefit can be measured in a natural unit (like number of saved lives),

The implementation of QALYs has been criticized for unjust discrimination towards e.g. older people who have less life expectancy than younger people, and people who happen to have a condition that is relatively expensive to treat [98]. Hence, it is argued that it violates the values that animate the health care service: that "each person is entitled to be treated with equal concern and respect both in the way health resources are distributed and in the way they are treated generally by health care professionals, however much their personal circumstances may differ from that of others" [98]. Proponents, on the other hand, argue that QALY maximization should be applied in the formulation of health care policy because "the planning of services will always mean that some groups of people will deliberately be deprived of benefits" as resources are not unlimited, and decision makers confronted with the complexity of alternatives need to carefully calculate benefits and cost without knowledge about the people who will benefit from their decision [97].

An inevitable concept in this way of thinking is the so called *opportunity cost*. Opportunity cost is "the value of a resource in its most highly valued alternative use" [7, p. 239], in other words the value of the next best choice of utilizing a certain resource or product. Opportunity cost is not limited to financial costs, but should include costs of output forgone, lost time and other kinds of lost benefits, and it plays a crucial role in ensuring that scarce resources are used efficiently.

1.6.5 The relevance of utility and utilitarianism as a normative perspective

In the following I will argue that that utility and utilitarianism provide a relevant and reasonable perspective of the normative discussions in this study for a number of reasons. First of all, the main reason for addressing the issue of utilization of imaging concerns the issues of benefits, risks of harm, and costs (see Section 1.2). Surely utilitarianism does not delimit utility to these concepts or to utility within a health context (see the previous section), but, to my knowledge, there is no other ethical theory that addresses these issues as clearly as utilitarianism. The importance of benefits (in the shape of health outcome), risks of harm (in the shape of pain or suffering) and costs for society is reflected both in research, and in professional and public debates. Although there are some concerns about underuse of diagnostic imaging, main attention has been directed towards over-utilization, inappropriate

a procedure-specific unit (like speed of healing of a wound) or a generic unit (like QALYs). The latter is actually the more subtle outcome measure in CUA, so it is hard to distinguish between them in practice [ibid].

use and factors compromising the utility of services. The questions related to usefulness and over-utilization of imaging services are also a common underlying theme in our research. Another common feature is that all our studies are based on quantitative empirical research. A utilitarian perspective should easily allow for making use of such research findings in a normative discussion, as empirical data is especially important in consequentialism [99].

Another argument for choosing utilitarianism is that it represents a "from within" perspective, because the utility perspective is important and influential in the reasoning of two of the main actors regarding utilization of imaging: the policy makers and the professionals. This does not mean that professionals are assumed to think maximization of overall utility in their daily work, but rather that they follow rules and think of the clinical utility for the individual patient. (How to understand utilitarianism in clinical practice is further explained in Section 2.3). I will not argue that the influence of utilitarianism is necessarily a good thing, which should also follow from the previous sections. Nevertheless, it seems relevant to address questions about utilization of imaging within a perspective that is highly influential in today's health care. It is likely that the focus on utility will increase in the future, as the gap between needs (and/or demands) and resources widens, largely due to the increase in medical possibilities and the increase in the proportion of elderly people in the population. Radiological services may be especially vulnerable in this respect, because of their instrumental value, and thus the difficulties of detecting their impact on final health outcome.

Beauchamp and Childress [100] describe how utility is important to the professionals through the principle of beneficence. [18] This principle is an implicit assumption in medical and health care professions: "Promoting the welfare of patients – not merely avoiding harm – expresses medicine's goal, rationale, and justification" [100, p.173]. To do more good than harm is reflected in radiation protection policy and legislation, which are familiar to practitioners in radiology. The central position of utilitarianism in radiation protection policy [101] [19] is pronounced in the following quotation from the Radiation Protection Directive:

> "Medical exposure […] shall show a sufficient net benefit, weighing the total potential diagnostic or therapeutic benefits it produces, including the direct health benefits to an individual and the benefits to society, against the individual detriment that the

[18] However, the principle of utility of Beauchamp and Childress (they discriminate between two principles of beneficence: *positive benefit* and *utility*) deviates from classic utilitarianism in not being an absolute and preeminent principle, but one of a number of prima facie principles [100].
[19] Utilitarianism is said to be downplayed in newer radiation protection policy and individual rights given more emphasis, focusing on individual radiation doses [101].

> exposure might cause, taking into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionizing radiation." [102]. [20]

An addition reason why the utility perspective is important to professionals is that lack of usefulness or futility violates the professional standards upon which the "medical exception" rests. According to Moratti [104], the reasoning goes as follows:

i) The doctor's "medical exception" is a non-statutory (or implicit) exclusion of medical behaviour from the coverage of those provisions of the criminal law that protect the integrity of the body.

ii) The medical exception does not prescript behaviour, this "is left largely to self-regulation by the medical profession."

i) This professional autonomy requires that doctors "intervene in accordance with professional standards".

ii) Professional standards include criteria of appropriateness in giving medical care laid down in official clinical guidelines [21]…based on a combination of scientific evidence (e.g. clinical studies or practice guidelines) and medical ethical considerations concerning patient welfare.

iii) Performing futile interventions would violate medical professional standards, i.e. amount to an invasion of the patient's physical integrity not justified by "medical exception".

Finally, the utilitarian perspective allows me to pursue (beyond the limits of journal articles) some of the interesting questions that arose in the project, for example: what are the consequences of current rules/norms influencing utilization of imaging, and what can be done to maximize the utility of services?

[20] In the Norwegian guidance, this reads: "Use of medical x-ray examinations is justified if the use of radiation predominately is useful to the patient with respect to expected diagnostic and treatment result, in proportion to the harm the radiation can cause. The assessment can include the expected quality and effectiveness of the result, and benefits and risks associated with alternative methods that entail lower doses or that are not based on ionizing radiation" [103] (my translation).

[21] According to Eddy [105] there are slight differences between the concepts. Compared to standards (which must always be followed), guidelines "*should* be followed in *most* cases [..., but] *can* and *should* be tailored to fit the individual needs"[105].

1.6.6 The role of empirical research in (current) normative analysis

Empirical data of different kinds, not necessarily collected for the purpose of ethical research (e.g. statistical studies of resource allocation) are commonly used in normative ethics [106] for a number of reasons. [22] I will sketch some of the roles empirical data can play in bioethics, before delimiting the role of empirical data for the normative discussion in this dissertation.

According to Holm [99,106], empirical data can be used in bioethics in three different ways. First, and most controversial, empirical data can place restrictions on moral theory, e.g. a moral theory cannot be valid if it requires from the moral agents something that is unrealizable. The argument is that norms that put moral obligations on people must be within what actually is possible for human beings, which is in accordance with the "ought implies can" principle. [23]

Second, empirical data can influence "the problem space of bioethical considerations" [99, p. 5]. By simply describing a practice or phenomenon, empirical research can assist in identification of ethical problems or direct attention to subjects or problems that receive little ethical consideration [108]. [24] Bioethics must address problems of practical importance (i.e. problems that are frequent, have serious consequences or bother practitioners) if it is to have an impact "on what happens in the world" [99, p. 5].

Third, empirical data can make bioethical analysis realistic [99]. This is important, because bioethical analysis usually addresses questions that are not purely conceptual, e.g.: questions of "which form of legal or quasi-legal regulation best promotes or supports a certain desired goal is not a purely conceptual question, and the question of which form of organisational re-engineering can create desired changes" [99, p. 6]. When aiming to have a practical impact, such analysis must be realistic and take account of features of the practice in question (like time constraints etc.). Empirical research can provide such information by describing and explaining the practice, e.g. by focusing on the mechanism underlying the practice [109], or motivation underlying attitudes or choice of action [108].

[22] The value of empirical research in bioethics has been controversial, but it is beyond the scope of this study to clarify the many ways of understanding the relationship between the normative and the empirical. I will just mention that three of the central aspects are: how the world *should be* cannot be derived from *how it is*, ethical theory must rest on some empirical premises, and no empirical research is value free [107].

[23] Not all bioethicists would agree on the 'ought implies can' principle, and it is difficult to "explain which kind of "cannot" implies which kind of "no obligations"" [99].

[24] Ethical dilemmas that have received little attention in bioethics are: "treatment refusals, financial conflicts of interests, time constraints, testing and treating because of legal concerns, difficult patients" etc. [108].

Both the second and the third points are relevant for the empirical data on utilization of imaging. However, to pursue both aspects would be too comprehensive, and I will emphasize the latter point – to make the normative analysis realistic – in the normative discussion here. This approach is in accordance with the overall aim of improving our understanding of the utilization of imaging and its utility, because it allows features of the practice to be in focus, rather than the normative theory (utilitarianism). Besides, the quantitative empirical research was designed to provide information about the practice (not to explore the problem space of bioethical considerations), which makes it well suited to inform a normative discussion of this practice.

1.7 Concepts and understanding of utility in imaging

Within the concrete context of radiological services, it is intuitively reasonable to think of welfare in term of good health outcome, but the delimitation of utility of imaging is far from straightforward. Hofmann has outlined the multitude of concepts describing excessive or "too much" examinations and categorized them by seven distinct aspects, of which one is utility [110]. The utility aspect includes both *usefulness* (benefit) and *need* (necessity) [110]. However, the categories are not absolute and concepts like appropriateness [25] or risk (reasonably categorized as a moral and a safety aspect, respectively) may also be relevant in an understanding of utility of imaging examinations. Moreover, the concepts and understanding may vary depending on whether they appear in a medical (including radiological) or a radiation protection context, which in turn may differ from the ethical concepts.

Within the medical community, common concepts to describe usefulness, in the meaning 'should be performed', are (medically) *necessary*, *appropriate* and *indicated*. The term *medical necessity* "generally refers to whether a health service should be used in a particular instance or for a specific person" [111]. However, the three concepts are used more or less synonymously and refer to whether the requested examination is judged to be in accordance with clinical guidelines and professional standards. The crucial question is whether the examinations are deemed likely to contribute clinically to the patient's treatment [112]. One

[25] Defined in health case as "care for which the expected health benefit exceeds the expected negative consequences by a wide enough margin to justify treatment" [15].

representative definition is: "A useful investigation is one in which the result – positive or negative – will alter management or add confidence to the clinician's diagnosis" [113].

This definition has some important characteristics. First, it expresses medical utility seen from the referring physicians' perspective. Though the underlying aim is benefit to the patients, it is the usefulness for the clinician that is decisive, i.e. it does not take into account that what is regarded useful may differ between the involved parties. Second, we notice that the usefulness is determined when the results are given. Hence, the referring physician must consider the possible outcomes and prospectively estimate their likelihood at the time the decision is made. Third, the definition further indicates a close relationship between utility and uncertainty, as the utility of an investigation depends on its ability to reduce the clinicians' uncertainty about a) diagnosis and/or b) patient management. In other words, the usefulness and purpose of the investigation is to reduce uncertainly.

The concepts *appropriate* and *indicated* primarily concern the clinical value of the investigation, but are also linked to the weighting of benefits against risks: "By definition, risk is outweighed by benefit for appropriate …examinations" [14].

In the radiation protection context, utility is similarly understood as the result of balancing benefits, risk and costs, i.e. a utilitarian understanding as mentioned above. The key concept here is *justification*, which is achieved by net benefits of the examination to the individual patient and to society.

The concept of *necessary* or *unnecessary* (the more commonly used opposite in the context of diagnostic imaging) points towards waste and futility. This concept makes sense both in an economic and a radiation protection context: referring to wasteful expenditure of scarce resources or wasteful radiation exposure. Concepts frequently used that are synonymous with *unnecessary* are: overuse and misuse. This is surely controversial, because the "meaning and implementation [of medical necessity] vary substantially among providers, payers and patients" [111], raising the question of who is to decide, why and in what way. For this reason professionals can argue against labels like overuse and misuse, as they think the services should open up for the influence of non-professional assessments and provisions [61].

The notion *medical futility* is found in the ethical literature and refers to:

> "… medical intervention that might be performed without being medically indicated. …[It] appeared in the 1980s [and its] function was that of putting a limit to the increasing requests for treatment that patients felt entitled to make to doctors … [as] the principle of patient's autonomy was interpreted in a more and more radical way. … [and confusing] the right to *refuse* an intervention with the right to *demand* one." [104].

This description links utility and medical indications, i.e. lack of indications is a necessary condition for labelling an intervention as futile. The futility concept makes sense in the context of diagnostic imaging, but is rarely used in the radiology literature. [26] The reason for this may be that futility is confined to dealing only with life-saving and life-sustaining medical interventions [104].

In treatment futility one can differentiate between goal futility and value futility [114]. An intervention is *goal futile* when it "cannot alter the magnitude of the linking probabilities" between the initial and the outcome medical state of the patient [114]. *Value futility* arises when the linking probabilities can be modified, but without a likely net benefit, because even if the defined goal is achieved, it is "deemed not worth achieving" [114]. Hofmann argues that this differentiation has little to offer if we are looking for an objective and value-neutral measure of diagnostic futility [110]. However, with lower level of ambitions it may still be a meaningful differentiation for understanding futility in imaging, and for clarification when designing research and measures to improve the utility of imaging.

It seems as though goal futility fits with the most common way of understanding unnecessary imaging. The defined goal is to provide diagnostic information that can alter patient management (by detecting, confirming or excluding diseases), and if the probability of this is low, the examination can be judged to be futile. Goal futility may arise in imaging for a number of reasons, corresponding to causes of unnecessary use of radiological investigations, e.g. repeating investigations [113]. Value futility precisely describes the situation where the information can and does alter patient management, but the outcome may still not benefit the patient. This can be exemplified by cases where no treatment for the detected disease are provided and cases where a small detected lesion exposes the patient to a series of unnecessary follow-up examinations and possible overtreatment. Value futility may be harder

[26] A search in Medline (Ovid 3/9-09) using the MeSH-terms (Subject Heading) 'diagnostic imaging' or 'radiology' combined with 'medical futility' gave 20 hits, of which only two were journal articles focusing on imaging (the rest addressed (f)utility of treatment, were case-reports/editorials/letters, or both).

to come by due to the distance between the intervention (the examination) and the final patient outcome.

1.8 Possible harm from diagnostic imaging

Harm caused by diagnostic imaging might be harder to spot than the benefits, at least for people outside the professional environment of radiology. However, the risks involved are a major reason for concern about utilization and utility of imaging. CT examinations are of particular interest here, due to the relatively high radiation doses. In this section, I will illuminate the multifaceted picture of possible harm or risks involved, and indicate the magnitude of the risk when such information is available. The account is limited to known types of harm or risk to the persons and populations who are receiving the procedures, [27] hence I will not emphasize the risks of emotional distress, medicalization etc.

1.8.1 Radiation risks [28]

Radiation-induced cancer is the risk that has received the most attention within the professional environment, and is addressed in the radiation protection recommendations [21] and legislation [22]. The ALARA-principle (As Low As Reasonably Achievable) is a fundamental principle in radiation protection policy, and an important norm in the practice of diagnostic imaging. This principle is based on the understanding that there is also a risk with low doses (i.e. doses <100 mSv); expressed in the Linear no-threshold (LNT) model, where the risk of radiation-induced cancer is assumed to decrease linearly with decreasing dose without a lower threshold [116].

The scientific basis for the LNT model of radiation risk has been controversial, but is supported by experimental and epidemiological studies, in particular data from the atomic bomb survivors in Japan – the Life Span Study [3,21,40,116]. These studies are highly

[27] I will not address harm that might be discovered in the future, e.g. from new technology like MRI. MRI has been used for only a few decades, so that future harm is a subject of scientific *ignorance*. This is the existence of relevant, but yet unknown outcome that can be suspected beforehand, but only proven in retrospect [115].
[28] Here the term *risk* means the probability of adverse health effects of diagnostic imaging, following common terminology in radiology (probably stemming from the stochastic nature of radiation effects). This deviates from a more sophisticated discrimination between *risks* as quantitative probabilities in a known sample space and *uncertainty* when the sample space is known, but probabilities of events cannot be quantified [115].

valuable, because they include a large (non-selected) population in which approximately 30 000 survivors were exposed to low doses [116]. Recent findings from these studies show:

> " … significant increase in the overall risk of cancer in the subgroups of atomic-bomb survivors who received low doses of radiation, ranging from 5 to 150 mSv; the mean dose in this subgroup was about 30 mSv, which approximates the relevant organ dose from a typical CT study involving two or three scans in an adult. … [this] suggest that the estimated risks associated with CT are not hypothetical – that is, they are not based on models or major extrapolations in dose. Rather, they are based directly on measured excess radiation-related cancer rates among adults and children who in the past were exposed to the same range of organ doses as those delivered during CT studies" [40, pp. 2280-82].

The effective dose estimates for a single CT scan are often between 10 and 25 mSv, and many patients have been studied several times [3]. In the radiology context, apart from CT scans, high dose procedures include interventional radiology, barium enemas, nuclear medicine and PET scans. Procedures with substantially lower doses, e.g. a front chest x-ray with lung doses of ca. 0.01mSv, are however outside the dose levels with direct epidemiological evidence [116].

The studies of the A-bomb survivors have provided good evidence that low doses of ionizing radiation increase the lifetime risk of cancer, which is also supported by corresponding risk estimates from other large-scale epidemiological studies [40,117]. Brenner and Hall refer to a study reported by Cardis et al. of nuclear workers, which shows a significant association between radiation dose and mortality from cancer, and a significant increase in cancer risk from 5-150 mSv [40].

It has been argued that the controversy over the LNT model could be put to rest after the latest epidemiological findings [116]. However, this has not happened. The debate is still going strong between the opponents [118] and the proponents [119] of the LNT model, interpreting and drawing conflicting conclusions from the same research findings. The alternatives to the LNT model suggest that low radiation doses are less or not at all damaging and may even be beneficial. The opponents of the LNT model argue for the likelihood of a low-dose threshold and the protecting mechanisms of low doses [118]. The hormesis hypothesis "is defined by the effect at low doses being opposite to that elicited by higher doses" [120], e.g. small doses of radiation may promote health by decreasing the risk of cancer. I will not pursue the alternative models for risk estimates any further here, but it is important to be aware of this controversy, because it shows that our understanding of radiation risk is loaded with difficulties and uncertainties.

The International Commission on Radiological Protection (ICRP) [21], the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) [121], and a series of national bodies that have reviewed radiation risk, unanimously regard the LNT model as the most appropriate for radiation protection purposes for doses of about 100 mSv or less [116]. Also, the latest report from the Board on Radiation Research Effects (BEIR VII), in which a comprehensive review of available biological and biophysical data is presented, concludes that: "the preponderance of information indicates that there will be some risk, even at low doses, although the risk is small" [117]. X-rays are now also classified as a "carcinogen" by the World Health Organization's International Agency for Research and Cancer [3].

It is difficult to estimate additional lifetime risk of cancer after exposure to low doses and low dose rate, and the calculation will include assumptions and uncertainties [29]. The ICRP recommends "that the approximated overall fatal risk coefficient of 5% per Sv on which current international radiation safety standards are based continues to be appropriate for the purposes of radiological protection" [21, p. 55]. This methodology makes crude estimates [30] by multiplying collective dose estimates by a generic fatal cancer risk estimate, but allows for risk comparisons between dose distributions from different imaging techniques [116].

A more sophisticated method for estimating risk associated with doses from imaging is based on individually measured or calculated organ doses, on which "risks can be applied (ultimately derived from A-bomb survivors) that are dose specific, organ specific, age specific, gender specific and country specific" [116, p. 368]. The total risk is then the sum of all the organ specific risks. An illustration of the results from such estimations is provided by Brenner and Hall [40] and is included here as Figure 5. This shows the estimated risk of lifetime cancer mortality from a single head and abdominal CT scan.

[29] Uncertainty in risk estimates concerns both the dose for the given examination and the risk this dose may represent. E.g. the A-bomb survivors "were exposed to a fairly uniform dose of radiation throughout the body, whereas CT involves highly non-uniform exposure, but there is little evidence that the risks for a specific organ are substantially influenced by exposure of other organs to radiation" [40].

[30] The estimates are crude because "it assumes validity of the LNT hypothesis down to the lowest doses [… and because the risk] estimates based on effective dose are highly generic and include, for example, hereditary effects that are unlikely to be significant at doses relevant to diagnostic radiology. In addition the weighting factors used in the calculation of effective dose do not take into account the strong variations of radio-sensitivity with age and gender" [116].

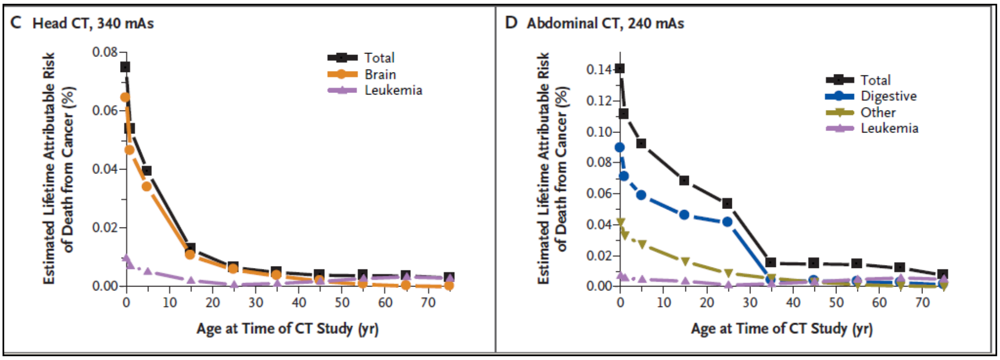

Figure 5: Brenner and Hall explain that: “Panels show the [...] estimated lifetime percent risk of death from cancer that is attributable to the radiation from a single CT scan; the risks (both for selected individual organs and overall) have been averaged for male and female patients. [...] The risks are highly dependent on age because both the doses (Panels A and B) and the risks per unit dose are age-dependent. Even though doses are higher for head scans, the risks are higher for abdominal scans because the digestive organs are more sensitive than the brain to radiation-induced cancer.” [40].

Figure 5 shows that lifetime risk of death from cancer attributable to radiological examinations is small. The lifetime attributable risk for *developing* a solid cancer or leukaemia (i.e. related to incidence not outcome) is equally small. For doses of 10 mSv it is predicted to occur in one individual in 1000 (0.1%), while the overall risk of developing cancer from other causes is approximately 40% [117]. The cumulative risk of cancer in the Norwegian population (up to age 75 years) attributable to diagnostic X-ray has been estimated to be 1.2%, which is equivalent to 77 cases of cancer per year [122]. This estimate was based on figures reported for 1993 [57]. As mentioned above, such estimates involve many uncertainties, so they should be interpreted with caution.

Another major conclusion drawn from the A-bomb survivor studies is that children are much more sensitive to radiation than adults [116], as illustrated in Figure 5. This can be explained by children’s high proportion of dividing cells and their many remaining years to live in which cancer induced by radiation can develop. The risk of lifetime cancer is approximately three times higher in early childhood than in the population as a whole [21]. The same estimates are considered relevant for embryos and foetuses [21].

1.8.2 Radiation effects other than cancer

Evidence of increased risk of diseases other than cancer has accumulated over the last two decades, particularly regarding heart disease, stroke, digestive disorders and respiratory disease [21]. However, the risk is uncertain at low doses, i.e. doses from near zero up to about 100 mSv [21,117]. The susceptibility of embryos and foetuses to lethal effects, malformations and mental retardation is judged to be very infrequent and unexpected at low doses [21].

The radiation protection authorities also judge *heritable effects* to be a risk from radiation exposure, i.e. the risk of inducing genetic disease in the offspring and future generations due to mutations of the germ cells' DNA. At low doses these risks are very small, and according to BEIR VII "one would not expect to see an excess in adverse hereditary effects in a sample of about 30000 children" [117].

Deterministic effects [31] (harmful tissue reactions) occur only with high doses of radiation, and are not expected in the dose range up to around 100 mGy [21]. However, skin reactions (from mild erythema to necrosis) have been reported after x-ray guided procedures, such as coronary angiography and intervention, which indicate peak entrance skin doses above 2 Gy [123].

In summary, radiation in diagnostic imaging involves a very small risk to the individual patient, and the benefits will certainly exceed the risks when the examination is justified. Nevertheless, there is rising concern within the professional environment about the rapid increase in the use of imaging (particularly CT examinations due to their relatively high doses) and the associated cancer risk [3,40,79,80]. The fear is that "small individual risks applied to an increasingly larger population may create a public health issue some years in the future" [40, p. 2281]. In particular, there is concern about the increasing use of CT in paediatric diagnosis, and in adult screening of asymptomatic persons [116]. In the latter case we lack the scientific documentation needed to be able to balance the potential benefit against the potential radiation risk [116]. It is noteworthy that this relatively new technology causes the greatest concern. In fact, modern CT machines offer "wide opportunities for increasing the

[31] *Deterministic* refers to early or late detectable tissue and organ reactions, requiring doses above a certain threshold (different for different injuries) and the severity of the effects is expected to increase with increasing doses [21, p. 159]. This differs from *stochastic effects* (radiation-induced cancer and heritable effect) resulting from damage in single cells, where increasing dose increases the frequency (i.e. the risk, not the severity) of effects, without a lower threshold [ibid].

radiation dose … (e.g. by obtaining overlapping spiral slices, repeated sequences during various phases after intravenous contrast medium...)” [80].

Awareness of radiation protection has generally been much higher in Europe than in the United States [69]. The increasing concern in the United States can be illustrated by the *Image Gently* campaign, which was started in 2007 by an alliance of individual radiologists, radiology technologists, medical physicists, and paediatricians, supported by their professional organizations [124]. This is a national education and awareness program aiming to reduce radiation doses from CT examinations [124]. One important aspect is to use CT scan only when necessary. According to a straw poll of paediatric radiologists, one third of CT examinations could be avoided by changing to an alternative investigating approach with or without imaging [40]. In Europe, where radiation-based examinations are governed by radiation protection legislation, there is still a need for limiting the use of CT procedures that are not clinically justified [82].

1.8.3 Risks of contrast agents

Iodinated contrast agents are commonly used in many radiological procedures (e.g. CT, MRI and angiography), and involve risks of anaphylactoid and non-anaphylactoid reactions, contrast-induced nephropathy and extravasation. Anaphylactoid reactions [32] with symptoms like urticaria, bronchospasm, and hypotension can occur in anyone, but are twice as likely in patients with asthma or other allergies [125]. Non-anaphylactoid reactions include “nausea and/or vomiting, neurotoxicity, cardiac toxicity, local pain, hypotension, and vasovagal reaction”, and debilitated patients are most susceptible [126]. Contrast-induced nephropathy is a serious risk, caused by “direct tubular cellular toxicity and changes in renal hemodynamics” [125]. It can be defined as “a rise in serum creatinine (Cr) levels 25% to 50% above baseline” [125]. Reported incidences are ca. 3% for the general population and 40%-50% for patients with known risk factors [125]. The most significant risk factor is pre-existing renal insufficiency. The condition is usually reversible, but may result in chronic renal impairment in up to 30% of the cases, and infrequently long term dialysis is needed” [125]. To prevent acute renal failure, it is important to identify patients at risk and in these cases limit the iodinated contrast media volume and maintain adequate hydration [125]. Extravasation is

[32] These are not true allergic reactions “because immunoglobulin-E antibodies to iodinated contrast media cannot be found in most patients experiencing signs and symptoms” [125].

reported to occur in ca. one in every 233 CT scans, with blistering and ulceration etc., in some cases surgery is required [126]. In general, today's nonionic iodinated contrast agents are considered safe, the reported risks of severe and very serious reactions are 0.04% and 0.004% respectively, while death occurs in 1:170 000 patients [127].

Gadolinium-based contrast agents (GBCA) in MRI procedures very rarely induce reactions resembling an "allergic" response. The frequency varies between 0.004% - 0.7% [127]. Extravasation is also less likely due to smaller volumes and less rapid administration of GBCA than iodinated contrast agents [127]. The risk of nephrogenic systemic fibrosis after the use of GBCA has been a subject of concern since it was first observed in 1997 [126,127]. This is a rare systemic disease (500 cases reported worldwide), which occurs almost exclusively in patients with severe chronic kidney disease, but it may result in severe disability and mortality, and there is no consistently successful treatment [126].

1.8.4 Risks from false and uncertain results and unexpected outcomes

Like all medical interventions, imaging radiology can give erroneous results. For example, there is a risk that small bronchial neoplasms are overlooked or wrongly interpreted as benign (false negative) in chest X-rays, which may be a significant cause of delay in treatment of lung cancer [4]. The problem of false positives is that they may lead to inappropriate patient management and follow-up procedures that are invasive, risky and expensive [128]. The proportion of false positive results is higher relative to true positive results when the prevalence of disease in the tested population is low [83]. Accordingly, low probability of disease will decrease the test's positive predictive value, which is defined as the proportion of test positive patients who actually have the disease (true positive / true + false positive). This is why test performance is likely to be relatively poor when patients are referred with the purpose of excluding or ruling out disease [83]. The risk of false negative results may be less likely, as the technology makes it possible to detect increasingly smaller abnormalities.

Detection of unexpected radiological findings, unrelated to the patient's primary problem, may be beneficial if they are dealt with and lead to improved health outcome, but so-called incidentalomas also represent a risk of harm [78]. Possible harm arises, because the "discovery of an incidentaloma usually results in further investigations and sometimes other interventions that in most cases end up demonstrating that the finding is of no clinical significance", i.e. a cascade effect [129]. The "patient may lose autonomy, pressured by fear to engage in further diagnostic and therapeutic procedures of uncertain value" [78]. Both the unexpected findings and the follow-up investigations and treatment can cause anxiety and physical harm [78], the latter because we may provide risky treatment without any medical benefit to the patient [128]. This is particularly unfortunate if the imaging was not indicated in the first place [129].

This problem area will probably increase with liberal use and can be seen as a consequence of technology development; "we see more things …[and] finding things makes doctors and patients more enthusiastic about doing the tests and seems to justify them" [8, p. 36]. A study of Furtado et al. indicates that the risk of incidentalomas is high. They analysed the reports and recommendations from whole-body CT screening of 1192 patients (76% of the patients were self-referred) and found that 86% had at least one abnormal finding, the mean number of findings per patient was 2.8 and 37% of the patients were recommended for further evaluation [130]. The saying "a healthy person is a person who has just not been thoroughly examined" might be about to lose its comical touch. Sörensen [131] describes a case where a PET/CT identified no less than six more or less certain additional pathological conditions, which left the physician with several difficult questions about how to handle this information: Should the findings be trusted? Which of the findings should be followed up? How much does the patient want to know? When should the patient be informed?

Problems related to incidentalomas are overdiagnosis, iatrogenic pseudodisease, clinically irrelevant cancer, or lanthanic disease. These are almost interchangeable terms referring to a pathological finding without clinical importance [132]. During their lifetime, patients would never be aware of pseudodisease if the diagnostic test had not been performed, and the phenomenon is caused by the increased capability and capacity of diagnostic testing [9]. Pseudodiseases are preclinical diseases that either do not progress (or actually regresses), or progress so slowly that the patient dies of other causes before they produce any symptoms [10]. From autopsies, we know that pseudodiseases exist in abundance [10]. It "is increasingly clear that the population living with an occult disease is many times larger than the population destined to become sick from it" [9]. [33] The problem is the resulting unnecessary treatment

[33] Fisher and Welch illustrate the potential for overdiagnosis by examples: MRI reveals knee abnormalities in 25% of young adults, and lumbar disk bulge (without pain) in half of us, ductal carcinoma in situ may be present in up to 40% of women in their 40s, and every second man in their 60s has adenocarcinoma of the prostate [9].

that occurs because it is impossible to distinguish pseudodisease from preclinical disease that would eventually cause clinical symptoms and disease [10,133]. Overdiagnosis has been most debated with regard to mammography screening, but is also recognized in screening for cancer of the prostate and lung cancer etc. [133].

2 MATERIAL AND METHODS

Two nationwide empirical quantitative surveys were conducted in the present study. The first was a survey of numbers of radiological procedures. This survey had two purposes: to monitor development of frequencies of radiological examinations and associated changes in population doses (study aim I) and to examine geographical variation in examination frequencies (study aim II). The second survey was a questionnaire. The questionnaire was sent to radiologists to obtain their perception of factors that influence the use of radiological services (study aim III), how they respond to inadequate imaging referrals and what factors affect their decision about whether or not to prevent examinations of doubtful usefulness (study aim IV). Core information on data material and the respective methods applied is given in the articles, and additional information is given in this chapter. Methodological considerations and challenges in both surveys are discussed in Chapter 4.

2.1 The survey of examination frequency

The Norwegian Radiation Protection Authority (NRPA) was the responsible institution for conduction of this survey. NRPA has surveyed examination frequencies and patient doses periodically for many years in Norway. This information is valuable for supervising the activity and for giving feed-back to the radiological institutions, but is also of international relevance, being used in analyses of differences between countries and health care systems [44]. For such reasons it is mandatory for the institutions (by regulation) to provide information on request from the NRPA regarding questions concerning radiation protection [22].

A Norwegian report [134] provides detailed information on how the survey material was collected, prepared, analysed and assessed. In the following sections, the main points concerning choices and considerations about data collection, preparation and analyses are presented, while quality assessment is discussed in Section 4.1.

2.1.1 Data collection

The number of radiological procedures for the year 2002 was requested from all Norwegian hospitals, private radiological institutes and mammography screening laboratories. This means that examinations performed in primary care, chiropractic settings, reception centres for asylum seekers (x-ray screen films) and dental services were excluded. Nuclear medicine and bone densitometry were also excluded. [34] As the addressees were the radiological departments at hospitals, the study did not include the use of radiology elsewhere (e.g. surgery and emergency departments).

50% of the institutions replied within the time limit, and all of them replied after three reminders by mail and telephone. This totalled 131 institutions: 72 public hospitals, 9 private hospitals, 25 private radiological institutes and 25 mammography screening laboratories.

Files or printouts from the Radiology Information Systems (RIS), where examinations are recorded according to the Norwegian Radiological Codes system (NORAKO) were requested. The system for coding examination has been developed over many years by the Norwegian Society of Radiology and in cooperation with KITH (Norwegian Centre for Informatics in Health and Social Care). NORAKO was a new national version implemented in 2002, based on earlier versions and other similar coding systems. It was designed for reimbursement purposes, but was also expected to facilitate centralized radiological activity registration. However, as codes were pooled by similarity in resource expenditure when sent for reimbursement, data had to be collected directly from the institutions. This was also necessary to secure a complete count, as examinations for inpatients are not refunded by the National Insurance Administration.

For the purpose of studying time trends of frequencies of radiological examinations, it was important that the data format was comparable with earlier data collections. Besides providing detailed and complete data in a uniform format, the method was assumed to be convenient for the institutions because they could easily gain data from the RIS.

A pilot study was performed in the summer of 2003 to test the feasibility of the method for data collection. Fourteen hospitals were selected, representing all the vendors of RIS. They were asked questions regarding the possibilities of exporting NORAKO data from RIS to

[34] Dental radiology and nuclear medicine were not included in the previous nationwide comparable surveys by the NRPA. X-ray screen films at reception centres for asylum seekers were excluded because asylum seekers are not included in the figures of the Norwegian population. Bone densitometry was assumed to be relatively infrequent in 2002 and did not have a separate code in NORAKO 2002.

Excel (including both inpatients and outpatients) and also asked to send us such data files. Ten hospitals replied, and the result was promising: 80% reported in the requested format.

2.1.2 Data preparation

The concept examination is defined as the use of one single modality for investigation of one single organ (or organ system or anatomical region). [35] This corresponds to how NORAKO defined examination codes and how available dose surveys provide effective dose values for complete examinations. Most importantly, according to the NORAKO system one examination can generate more than one code. Hence, numbers of examinations were derived from numbers of codes by deleting the codes that only describe the procedure further or reflect the resources utilized, i.e. codes not representing an examination. The adjustments of the data material were based on:

- statements from the institutions
- the NORAKO user manual
- scrutiny of the data material
- a previous survey of CT examination techniques, which described the mean proportion of examinations with, without and both with and without intravenous contrast media for the most common examinations in 1995 [135].
- a follow-up inquiry where a sample of seven institutions were asked questions about coding practice and reporting according to the 2004 version of NORAKO. In this version the number of series should be coded in a separate code string.

In this section, I will describe how these adjustments were carried out, but as the NORAKO system is so essential for the method a short description of how this is constructed will be presented.

The NORAKO system provides detailed information of each examination. It consists of five code elements: modality (x-ray, CT, MRI or ultrasound), location (anatomic region, organ or organ system), procedure (that characterizes the examination e.g. use of contrast media), side (right, left or bilateral) and additional information (e.g. use of anaesthesia). The three first code elements are mandatory in the reimbursement system.

[35] This definition is in accordance with the more detailed one applied in European countries: "An x-ray examination or procedure is defined as one or more (a series of) x-ray exposures of one anatomic region/organ/organ system using a single imaging modality, needed to answer a specific diagnostic problem or clinical question during one visit to the radiology department or medical practice" [45, p. 95].

In the adjustment of the data material, we considered questions regarding four aspects: level of detail, more than one location in the same examination, more than one procedure in the same examination, and bilateral organs or limbs. Codes for additional information are generally used infrequently (in about 1% of the code strings). However we deleted all codes which clearly did not represent an examination, e.g. reinterpretation of radiographs.

Dealing with the level of detail

14 of the 131 institution did not report in the requested format. For six of these, examinations were coded manually based on received descriptive texts. For 8 (small) institutions that reported on examination group level (e.g. number of skeleton X-rays), average distributions for similar institutions were used to estimate the distribution of localization codes within each group. Cases where the NORACO system was used, but information about a code was largely missing or unclear (more than 20 cases), were clarified by a telephone call to the institution. [36]

Dealing with more than one location in the same examination

More than one location in the same examination concerns in particularly angiographies and interventions (where several blood vessels are involved) and also ultrasound examinations. [37] We tried to sort this out in the follow-up inquiry mentioned above, but unfortunately the replies differed substantially. Consequently, angiographies and interventions were counted by number of blood vessels/locations examined, which indicates overestimation.

Dealing with more than one procedure in the same examination

According to the user manual, procedure codes should be included in one and the same code-string unless more than one is used in the examination. However, the user manual was somewhat inconsistent by giving contradictory examples, i.e. examples where the procedure code was described in a separate (additional) code-string. Such inconsistencies did not occur for X-ray examinations. Procedure codes were not commonly used for X-ray (other than angiography) and ultrasound examinations. Only 11% of these include a procedure code. It was considered unlikely that a majority of these were part of examinations with several procedure codes or resulted from coding not in accordance with the user manual. Hence, for

[36] Examinations where modality or location codes were missing were included by coding them XM and XL. These constitute 0.08% of the total data material.

[37] In NORAKO 2002, so-called 'assembling codes' should be used in such cases, typically for abdominal ultrasound examinations.

these modalities the number of codes was assumed to be equal to the number of examinations. On the other hand, procedure codes are widely used for other modalities, in particular codes for additional series and intravenous contrast. According to examples in the user manual, additional series should be described in a separate code-string. Accordingly, these codes were deleted, except for six institutions where coding had clearly not been carried out in accordance with examples in the manual.[38]

For the procedure code intravenous contrast (IV), adjustments were made based on the previous survey of CT examination techniques [10] mentioned above. This study described the mean proportion of examinations with, without and both with and without intravenous contrast media for examinations of the thorax, abdomen, kidneys, liver, pelvis and head. We used these data to construct a norm of distribution for each type of examination and applied it to adjust our data for each institution separately. An example of how this was done is shown in Table 1.

Table 1: Number of codes for CT of thorax (TH) with and without procedure code for contrast media (IV) as reported from one hospital, norm of distribution from the survey by Olerud and Finne [135], distribution of codes according to the norm, and the resulting estimated number of examinations

Code	Number of codes	Norm of Distribution[1]	Distribution of codes	Estimated examination
TH	2 880	15/39	1 108	1 108
TH		24/39	1 772	1 772
TH IV		24/85	881	overlap deleted
TH IV	3 121	61/85	2 240	2 240
Total:	6 001		6 001	5 120

[1] The norm of distribution describes that 61% of CT of thorax was performed with contrast media and 15% without, while 24% was performed with two series, i.e. both with and without. In the latter group we deleted codes possibly double registered in two codes strings both with and without IV.

According to the 2004 version of NORAKO, the number of series should be coded in a separate code string. A main reason for collecting examination data coded according to this NORAKO version in the follow-up inquiry, was to assess our method for removing codes not representing an examination. The analysis of this new data material supported our adjustments, both regarding the locations that should be adjusted, that contrast media was the most important procedure code to take care of, and that the number of deleted codes was

[38] In these institutions the number of codes with additional series was higher than without, meaning that they could not possibly have coded examinations with additional series in two separate code strings. E.g. if the number of MRI head with additional series was higher than the number of MRI head without code for additional series, the codes that constitute the difference between the two sums must represent examination (coded incorrectly as only one string), which should not be, and was not, deleted.

reasonable. The reduction in codes for thorax, liver and head was appropriate, while the 2004 data indicate that codes for abdomen, pelvis and kidneys could have been reduced some more (more details are provided in Appendix 6 in the report from NRPA [134]).

The final results of adjusting the data material taking account of possible double coding of procedure codes are shown in Table 2.

Table 2: Overview of number of codes, estimated number of examinations and reduction of number of codes for additional series and in total

Modality	Number of codes	Estimated examination	Reduction of additional series (%)	Total Reduction[1] (%)
CT	562 447	475 537	7,7	15,5
MRI	465 775	277 118	44,8	40,5
X-ray[2]	2 908 407	2 902 069	0,2	0,2
Ultrasound	486 673	486 623	0,0	0,0
Missing	1 400	1 400	0,0	0,0
Total	4 424 702	4 142 747	5,8	6,4

[1] For MRI, the total reduction is smaller than the reduction of additional series because some examinations have been added to correct for under-coding in some institutions (see footnote 38).
[2] Within the modality x-ray, 91% of the reduction of additional series is angiography and interventions. Originally additional series codes in angiography and interventional codes was 8.7% (5 760) of total codes (65 951).

Dealing with bilateral organs or limbs

The use of side codes varied and was not obligatory, but the user manual advises using *B* (bilateral) when both sides are examined. It is possible that right (D – dexter) and left (S – sinister) has been used in such cases, causing overestimation of examinations. Lacking a valid method, we did not adjust for such incorrect coding practice. Also regarding the question of side code, the answers from the follow-up inquiry differed: some never use the *B* code (only *D* and *S*) and among those who use *B*, some count these as one examination, others as two examinations.

2.1.3 Estimating trends in frequency and doses

The frequency of examinations in 2002 was compared with findings from a similar survey in 1993 (Article I). Both surveys made use of the same coding system, though some codes had been added and some had been discontinued during the 10-year period.

The Collective Effective Dose (CED) measured in man Sievert (manSv) was calculated according to the formula $\Sigma_i E_i N_i$, where E_i is the mean effective dose to patients from a specific examination and N_i is the number of this examination. Estimates of mean effective dose for each examination type were predominantly obtained from Norwegian dose surveys carried out by NRPA (for 84% of the examinations) and published by Olerud et al. [57,136]. When national dose values were not available, the mean effective dose was derived from internationally published surveys (2% of the examinations), or estimated from a similar examination/procedure if no value had been published (14% of the examinations).

Trends in examination frequency and CED were analysed using plain descriptive percentage changes in examination rates (number of examinations per 1000 inhabitants).

2.1.4 Estimating geographical variation

County was chosen as the unit of analysis for geographical variation (Article II), assuming that most patients are examined in their home county. For two large hospitals with national function that are situated in Oslo (the Norwegian Radium Hospital Comprehensive Cancer Centre and Rikshospitalet University Hospital), [39] we obtained information about the patients' county of residence and the corresponding number of examinations per modality, which formed the basis for distributing these data to the counties. Moreover, three screening laboratories provided services in two counties each. Data from these laboratories were distributed according to the number of inhabitants in the respective counties.

Simple high/low ratio and coefficient of variation (COV, defined as standard deviation relative to mean rate value) were applied to describe variation in examination rates, and Pearson's r to describe correlations. The four hypotheses were tested as follows:

The hypothesis that counties with low use of one modality for examination of specific organs (locations) have correspondingly high use of other modalities was tested by correlations between the use of different modalities (plain X-ray, CT, MRI and ultrasound). This hypothesis is based on the assumption of a substitutionary, rather than a supplementary, use of

[39] These institutions were still two separate hospitals in 2002.

modalities. Here we included cases where two modalities were frequently used for the examination in question, i.e. more than 1 per 1000 inhabitants nationally.

Regarding the hypothesis that private institutions contribute to geographical variation, we scrutinized the contribution from public and private institutions in single examinations, and tested the correlation between COV of the 30 most frequent single examinations and the proportion of these examinations performed by private institutions.

For the hypothesis about impact of accessibility, we correlated examination rates per thousand inhabitants in the counties with different aspects:

- the percentage of the county's population living in a municipality where a general radiological provider was located [40] (indicating proximity to radiological services)
- the population densities (inhabitants per square kilometre)
- the proportion of urbane settlement (2000 inhabitants or more)
- the number of radiologists and the number of radiographers (measures of accessibility in the shape of available radiological resources).

The last hypothesis was tested by correlating examination rates with a) average gross income for persons 17 years of age and over, and b) number of persons with tertiary or postgraduate level of education per 1000 inhabitant.

In the analyses of possible association between examination frequency and different aspects of settlement, socioeconomic status and radiological resources in the counties, we made use of aggregated statistics from Statistics Norway [41], except for the number of working radiologists in each county. This data was obtained from the Norwegian Medical Association (NMA) (on personal request).

All tests were two-tailed and *P* values ≤ 0.05 were considered statistically significant. The question whether to adjust the *P* values for multiple tests is discussed in Section 4.1.5.

We used MS Access and Excel data software in all data preparation and analyses in the frequency survey.

[40] In general radiological services, mammography screening facilities and specialized rehabilitation and heart disease hospitals were excluded.
[41] Statistics Norway is available at http://www.ssb.no.

2.2 The radiologist survey

2.2.1 Study population for the radiologist survey

In order to include as many physicians practising in the field of radiology in Norway as possible, we obtained membership lists from the NMA. Most physicians in Norway are members of the NMA (96.8% of those under retirement age in 2007) [137]. The total number of current practising approved specialists and registered trainees in radiology was 564 in February 2007, not including those with addresses abroad, who were assumed not to practise in Norway.

These 564 physicians were invited to participate and (except for the 20 physicians in the pilot group) received the survey in mid April 2007. An introductory letter informed them about the purpose of the study and the confidential handling of the responses (see Appendix A). A return envelope with postage paid was also included to facilitate responses. All 544 physicians received a reminder four weeks later containing a new copy of the questionnaire. This was necessary because no respondent identifier was applied.

2.2.2 The questionnaire

The questionnaire was constructed based on a literature review, as no existing and tested tool could be identified. Literature on the study subject was collected over a period of several years. This formed the basis for deciding which topics should be included in the questionnaire, and which specific questions were relevant. The literature was particularly useful for identifying items to include for each question, i.e. to make the lists of items as complete as possible (e.g. the list of factors causing increased investigation volume). Most articles were found using Medline (via Ovid), and examples of core MeSh terms are given in Table 3. [42] I did not search exclusively for research articles, as comments and letters to the editor etc. are valuable sources of professionals' perceptions.

[42] I used the ordinary strategy combining single terms within each search area with *OR*, and combining the search areas with *AND*. Searches were also performed in EMBASE and directly in some radiologist journals.

Table 3: Examples of MeSh terms used for searching for literature when constructing the questionnaire

The specialty	The concern	The role of professional
Diagnostic Imaging	Utilization Review	Referral and Consultation
Radiology	Delivery of Health Care	Attitudes of Health Personnel
Radiology Department, Hospital	Health Services Misuse	Physicians
Radiography	Unnecessary Procedures	Physician Patient Relations
Tomography		Moral Obligations
Magnetic Resonance Imaging		Decision Making

The resulting draft of the questionnaire was assessed by and discussed with three expert radiologists. [43] The revised questionnaire was then tested with a group of radiologists at a university hospital. Through a contact person, the questionnaire was distributed to five radiologists, who were asked to read and answer the questionnaire individually and meet for a group discussion/feedback meeting six days later. [44] The discussion was recorded and transcribed. These two rounds of testing led to important improvements in both the content (e.g. appropriateness of the questions in a Norwegian context) and the format of the questionnaire. Finally, a pilot survey was sent to 20 radiologists randomly selected from the list of 564. This only lead to minor adjustments.

The final four-page questionnaire consists of four sections (see Appendix B). The first section (A) contains two questions about factors that influence the use of imaging: causes of increased investigation volume (Question 1) and unnecessary investigations (Question 2). These data were used in Article III. The five-point response scale was chosen to allow fine graded responses that would make sense to the radiologists. The response categories were labelled (to a very small extent, to a small extent, to some extent, to a large extent, to a very large extent) to make the questions less vague and thereby reduce the potential for measurement errors [138].

Section B focused on radiologists' participation in the decision-making process for imaging and included a question about how radiologists act when confronted with inadequate referrals (Question 5) and questions about factors that affect radiologists' decisions to prevent (Question 6) or not prevent (Question 7) an examination of doubtful usefulness. These three

[43] These radiologists were selected because we knew they were interested in the subject matter. While constructing the questionnaire, we also received feedback and assessments from research fellows, some experienced designers of questionnaires and statisticians. Concerning design and practical shaping of the questionnaire, useful advice was also found in Don A. Dillman's 'Mail and Internet Surveys. The Tailored Design Method' [138].

[44] One of the five radiologists was not present at the meeting, but had completed the questionnaire and had added remarks.

questions were used in Article IV. In Question 5, a four-point scale (daily, weekly, monthly and less often than monthly) was considered appropriate, while we kept the scale from Questions 1 and 2 in Questions 6 and 7. Response categories were merged for analysis purposes.

2.2.3 Data preparation and analyses

SPSS for Windows (version 14.0) software was used for all analyses. A code book was made and supplemented while preparing the data files. Incorrect and inconsistent completions of the questionnaires were handled consecutively and all decisions recorded to secure consistent handling. Quite a few minor deviations were found, [45] but no respondent was rejected due to general erroneous completion. To check for errors made when typing the data into the computer, printouts of the total data matrix were compared manually with the original returned paper questionnaires, using an assistant. [46]

Not using respondent identifiers and sending two copies of the questionnaire, introduced a risk of double registrations. To identify possible cases of this, a 'duplicate cases' analysis (an option in SPSS) was performed. This analysis identifies identical answers on a set of variables. Stable answers were expected on demographic and practice setting questions; hence Questions 11-17 [47] were included in this analysis. Sixteen possible duplicate cases were identified and compared with the completed questionnaires. Double replies were found to be unlikely, as there were differences in handwriting and substantial differences in the response pattern for the dependent variables.

[45] Typically unclear crosses were e.g. crosses which were only "half", doubled on one item or misplaced between two response categories. This latter problem was solved by choosing the reply most contrary to our hypothesis (or guess) of expected replies. Signs were also added (like: arrows →, parentheses ( ), more/less than < / >, approximate ca.). Most inconsistencies were found in Section D (see Appendix B). E.g. the question about how many years have you practised as a radiologist (Q 14) was ambiguous about whether to include the years in training. Question 13, about 'subspecialty/main field of work', appeared to be difficult to answer. 29 missing values were registered and 26 responders (contrary to the instructions) had put a mark on more than one of the alternatives.

[46] This resulted in corrections in 0.3% of the total matrix (84 out of 277 716 numbers (82 variables times 338 respondents. Some responses were received after this control)).

[47] Answers to the last option in Question 17 (other or additional subspecialty/main field of work) were coded as a separate variable. This was not included in the duplicate case analysis, because we assumed the reply here could have changed slightly between two replies.

Statistics

Frequency analyses were computed for the questions (items) used in the articles. The variables had a response scale at the ordinal or nominal level, i.e. categorical data (except for a few questions in the background section). Hence, cross-tabs and Chi-squared tests were preferred when evaluating possible associations between variables. We used Pearson's chi-squared test for dichotomized variables and 'test for trend' (linear by linear association chi-square) for ordered variables. The latter choice makes a more powerful analysis in these cases [139,140].

In addition, factor analysis was applied in Article III, to explore underlying themes in responses to the question about causes of increased investigation volume. [48] The most common form of factor analysis, principal component analysis with varimax rotation [140] [49] was used. We also followed recommended procedure by using the Kaiser rule of eigenvalues of >1.0 for determining the number of factors to include, and Kaise-Meyer-Olkin (KMO) statistics for assessing sampling adequacy. [50] The internal reliability of the new factors (i.e. latent variables) was measured using Cronbach's alpha. Respondents' factor scores were computed as the sum of weighted item scores, i.e. raw score on items included in the latent variable multiplied by the item's factor loading. [51] The inferential process of labelling factors based on factor loadings is challenging, and can be fraught with subjectivity [140]. Two researchers may impute different labels for the same set of factor loadings. Hence, researchers "may wish to involve a panel of neutral experts in the imputation process, though ultimately there is no "correct" solution to this problem." [140]. In our study it would be hard to establish a panel of neutral experts, due to lack of previous similar research. Instead, the factor labels

[48] The 5-point response scale in Question 1 was considered sufficient to allow for factor analysis, which requires interval or near-interval data [140].

[49] The purpose of rotation is to "make the output more understandable and is usually necessary to facilitate the interpretation of factors. … *Varimax rotation* is an orthogonal rotation of the factor axes to maximize the variance of the squared loadings of a factor (column) on all the variables (rows) in a factor matrix, which has the effect of differentiating the original variables by extracted factor. Each factor will tend to have either large or small loadings of any particular variable. A varimax solution yields results which make it as easy as possible to identify each variable with a single factor" [140].

[50] "The eigenvalues for a given factor measure the variance in all the variables which is accounted for by that factor" [140], and eigenvalue above 1 means that the factor can explain more of the variance between the variables than a single variable can. Kaiser-Meyer-Olkin (KMO) statistics can be used "to assess which variables to drop from the model because they are too multicollinear. … KMO varies from 0 to 1.0 and KMO overall should be 0.60 or higher to proceed with factor analysis" [140].

[51] An item's factor loading is the correlation coefficient between the item (or variable) and the latent variable (or factor) and "the squared factor loading is the percent of variance in that indicator variable explained by the factor" [140].

were determined by me and my supervisor (Bjørn Hofmann), after scrutinizing each set of factor loadings carefully and then discussing the suggested labels thoroughly.

We analysed associations between the resulting factor scores and background variables using T-tests (in dichotomy variables) or Spearman rank correlation. Spearman rank was also used in analyses of correlations between these latent variables and responses to Question 2 – causes of unnecessary investigations. All tests were two-tailed and a *P* value of ≤ 0.05 was regarded as statistically significant.

The study had approval from the Norwegian Data Inspectorate, Norwegian Social Science Data Services (NSD) (reference: 16082). [52] Approval from the Regional Ethical Committee was not required, as neither of the surveys concerned "medical and health research on human beings, human biological material or personal health data" [141].

2.3 Limitations in the normative perspective

The normative agenda of this dissertation is to bring empirical knowledge about utilization of radiological examinations into considerations about its utility. A utilitarian perspective, as described in Section 1.6, appears to be the normative perspective most relevant and suitable for this purpose. In the following, I will outline some limitations and considerations for applying this perspective.

Above, I have described different variants of utilitarianism, and also non-utilitarian consequentialism. The understanding of utilitarianism that will be used in this dissertation is close to Richard Hare's two-level approach. This is because the utilization of diagnostic imaging needs to be discussed both at a clinical level and a policy level. In day to day clinical practice, rules are needed to avoid that decisions about the utility of a radiological examination depend solely on the assessment of the individual actor (clinician and radiologist) and to accommodate the criticism of time-consuming act utilitarianism (Hare's level 1). However, at the policy level, sufficient time and other resources should be available

[52] The data from the group discussion to improve the questionnaire did not contain any person identifying information, and records and transcripted text were deleted. Nevertheless, this step in the project should have been reported as a change to NSD, because a computer was used when listening to and transcribing the recorded discussion, instead of a traditional tape recorder. NSD was contacted in retrospect, but did not need a report of the change, as the data had been deleted.

to consider carefully questions regarding utility of diagnostic imaging services. It is also most important to assess critically the rules that influence (or aim to influence) utilization (Hare's level 2). The approach of the normative discussion here is to illuminate and analyze critically, at Hare's level 2, some possible consequences of increasing utilization of diagnostic imaging and of the rules and norms that aim to influence utilization.

In Section 1.6, I have described several limitations of utilitarianism. The practical implications of these here are twofold. First, the discussion cannot possibly cover all expected consequences for all involved parties. When selecting the focus for the discussion, I find it important to contribute to the debate about utilization of diagnostic imaging. One way of doing this is to address the main questions raised in this debate, which is (as previously explained) questions about benefits, risk of harm, and cost of the services. Benefits and risk of harm in this context are primarily a question of possible health outcome and well-being of the patients receiving the services, while the costs concern the benefit to society at large. Therefore, I believe that the following three dimensions of outcome of increased imaging capture the main concerns: 1) Does increased use lead to improved health for the population or subgroups of the population? 2) Does increased use lead to less pain? [53] 3) Does increased use lead to lower costs for society? This limitation excludes assessment of patients' preferences as such, i.e. the positive consequences of satisfying patients' wishes for a radiological examination irrespective of expected health outcome. As described in Section 1.5, the role of patient autonomy in the decision-making process is part of the debate on utilization of imaging. The reason for still making the limitation is that utility of health care services is primarily understood in terms of clinical health outcome, and satisfaction of preferences is controversial as an aim for the Norwegian health care system. However, the question of consequences of compliance with patients' wishes is addressed, insofar as this contributes to examinations for comforting purposes, and is discussed in relation to reduction of mental pain. Management of utilization is another topic of debate and research within the field of diagnostic imaging. This follows from concern about the outcome of the services. Accordingly, I find it appropriate to discuss the utility of different norms and measures (existing and suggested) to influence or manage utilization.

[53] It can be argued that less pain will lead to improved health outcome, but this is not necessarily true. The concept of health is too complicated to address here, but it is more comprehensive than pain, and does not presuppose being free of pain. It is perfectly possible that pain reduction may not alter health outcome. When these topics are discussed separately here, it is also because the dichotomy of well-being (here health) versus suffering and pain is central in utilitarianism.

Second, the discussion cannot be summed up in any numerical calculation of overall utility. A comprehensive quantification and comparison of all the possible outcomes would require a common unit for measurement of utility and sufficient information to give each outcome a value on this unit. As described above, attempts to make such calculations are controversial. Apart from the moral problems, there are practical problems in the case of diagnostic imaging, as I cannot see that we have sufficient information to calculate overall utility in any meaningful way. At any rate, the empirical research on which the discussion here will draw, by no means provides data suitable for numerical estimates and comparisons of the value of the different outcomes. The empirical research findings that will be applied are primarily the studies presented here. None of this research has investigated consequences related to utilization of diagnostic imaging or measured its utility directly, but the findings provide information that give relevant indications about utility. Other research findings will be included in the discussion, because they provide complementary perspectives and will improve the sustainability of the analysis. Some of this research contributes with measures of single aspects of utility. Nevertheless, the sum of empirical findings included is too complex to make any calculation of overall utility. Still, it makes it possible to indicate some tendency regarding overall utility. In utilitarianism, the calculation of overall utility can be seen as an ideal aim, and lack of such calculations does not hinder one from applying a utilitarian perspective for assessing and discussing a topic or a practice.

The approach implies an element of "evaluation" of the practice, but is not equal to a moral evaluation where the purpose is normally to pass judgement on the morality of the practice [109]. It must be underscored that this is not the purpose here. Rather, the hope is to inform, and to contribute to realism in the debate on utilization and utility of imaging services, by discussing the issues informed by empirical research.

3 SUMMARY OF RESULTS

3.1 Article I

Børretzen I, Lysdahl KB, Olerud HM.

Diagnostic radiology in Norway – trends in examination frequency and collective effective dose

Radiation Protection Dosimetry 25 May 2007

Activity data from Norwegian radiological institutions were collected for 2002. Examination frequencies and updated collective effective dose estimates (CED) were compared with corresponding figures from 1993.

We found that overall examination frequency increased by 16% (from 0.79 to 0.91 examinations per inhabitant). The largest increase in examination frequency occurred in MRI (10-fold increase), followed by CT (more than doubling) and mammography (nearly 70% increase). The contribution to CED from radiological examinations was estimated to be 1.1 mSv per inhabitant, representing a 40% increase during the decade. This is caused by the increase in CT examinations. The contribution of CT examinations to collective effective dose estimates was 59% in 2002 as opposed to 30% in 1993.

In the article, we argued that new imaging technologies tend to supplement rather than replace conventional technologies. Furthermore, the CED is relatively high in Norway despite overall frequencies similar to those in other European countries. This can be explained by high accessibility of CT scanners and calls for attention from a radiation protection perspective. We concluded that regularly monitoring the use of radiological examinations (including both examination frequencies and updating of dose data) is important and in accordance with newer requirements for dose optimization and registration in the Norwegian radiation protection regulations.

3.2 Article II

Lysdahl KB, Børretzen I

Geographical variation in radiological services: a nationwide survey

BMC Health Services Research 15 February 2007

In this study, we compared examination frequency between Norwegian counties based on the same data material as in Article I. We analysed differences in examination frequency according to contribution from public and private institutions in the counties, and the impact of accessibility and socioeconomic factors.

We found that overall examination rates per thousand inhabitants varied by a factor of 2.4. The use of MRI varied from 170 to 2, and CT from 216 to 56 examinations per 1000 inhabitants. The variations were less for conventional x-ray and ultrasound, but still significant, with high/low ratios of 2.0 and 2.9 respectively. Single MRI examinations (knee, cervical spine and head/brain) ranged high in variation, as did certain other non-MRI spine examinations. For examination of specific organs, the counties' use of one modality was positively correlated with the use of other modalities, i.e. not supporting the hypothesis that high use of one modality substitutes for low use of another. Private institutions accounted for 28% of all examinations, and tended towards performing a higher proportion of single examinations with high variability. Indicators of accessibility (the proportion of the counties' population living in municipalities with general radiological services, population density, proportion of urbane settlement, number of working radiologist and radiographers) correlated positively to variation in examination rates, partly due to the figures from the county of Oslo. Correlations between examination rates and socioeconomic factors were also highly influenced by the figures from this county.

We concluded that the substantial variation in examination frequencies could be partly explained by differences in accessibility, coexistence of public and private institutions and socioeconomic factors. The findings represent a challenge to the objective of equality in access to health care services, and indicate a potential for better allocation of overall health care resources.

3.3 Article III

Lysdahl KB, Hofmann BM

What causes increasing and unnecessary use of radiological investigations? A survey of radiologists' perception

BMC Health Services Research 1 September 2009

In a postal questionnaire we asked Norwegian radiologists to rate suggested causes of increase in investigation volume and causes of unnecessary investigations.

We found that the highest rated causes of increasing use of radiological investigations were: a) increased possibilities due to new radiological technology, b) peoples' increased demands for certain knowledge about own health, c) referring physicians' lower tolerance for uncertainty, d) expanded clinical indications for radiology, and e) increased availability of radiological equipment and personnel. A factor analysis of the suggested causes identified five latent variables 1) *referring physicians' uncertainty*, 2) *efficiency and economy*, 3) *patients autonomy and legal claims*, 4) *medical possibilities*, and 5) *health market.* Only a few weak associations were found between these latent variables and subgroups of radiologists.

The respondents rated over-investigation (to reassure referring clinicians and patients) and insufficient/unclear referral information as the two most frequent causes of unnecessary investigations at their own workplace. 50% of respondents reported these to occur to a large extent and 42% to a very large extent. Compared to hospital radiologists, radiologists in radiological institutes consistently reported lower occurrence of causes of unnecessary examinations.

The causes of unnecessary radiology use were positively correlated with two of the latent variables explaining increased use: *referring physicians' uncertainty* and *health market*.

We claim that the radiologists' perspective underscores topics important for managing the growth in investigation volume and limiting inappropriate investigations. These are supply and demand-related issues, and support in the decision-making process.

3.4 Article IV

Lysdahl KB, Hofmann BM, Espeland A.

Radiologists' responses to inadequate referrals

European Radiology 7 April 2010

The same questionnaire as in Article III contained questions about radiologists' reasoning and actions when confronted with inadequate referrals. The radiologists graded the frequencies of actions regarding referrals with ambiguous indications or inappropriate examination choices. They also graded the contribution of factors a) preventing and b) not preventing an examination of doubtful usefulness from being performed as requested. Responses were compared between specialists and registrars, and between radiologists employed in hospitals and private institutes.

Of 361 currently practising radiologists, 344 (95%) reported daily or weekly actions against inadequate referrals. Actions varied between subspecialties. The most frequent actions were contacting the referring physician to clarify the clinical problem, and to check test results and/or information in the medical record. Both actions were more frequent among registrars than specialists and among hospital radiologists than institute radiologists. Institute radiologists were more likely to ask the patient for additional information and examine the patient clinically. Compared to registrars, specialists more often returned the referral and gave a reason for the refusal. The highest graded factors preventing doubtful examinations were: high risk of serious complications or side effects, high radiation dose and low patient age. Factors facilitating doubtful examinations had less impact, but included respect for the referring physician's judgment, patient/next-of-kin wants the examination, patient has arrived, referring physician is difficult to contact, and time pressure.

We concluded that radiologists frequently take action in response to inadequate referrals mainly by searching for complementary information. Their actions seem to be mainly motivated by patient safety considerations. Vetting of referrals at arrival, easier access to referring clinicians, and sufficient time for radiologists to handle inappropriate referrals, may contribution to improved use of imaging.

4 ASSESSEMENT OF THE METHODOLOGY

The discussion of methodology is structured according to the challenges and limitations of the two surveys. Validity questions related to the instruments, the samples, the calculations and the statistical methods are the main issues. Mainly, issues that are not sufficiently covered in the articles are addressed. But first, I wish to say a few words about choice of research approach.

It may be more obvious that a quantitative approach is appropriate for the examination frequency study than for the radiologist study. One could, for instance, argue that radiologists' perception of factors causing increased investigation volume calls for a qualitative approach, as this has hardly ever been investigated systematically before. However, a multitude of such factors are described and discussed in the literature, including in the radiologists' journals. These factors could be used in a quantitative approach. We cannot guarantee that new factors would not have emerged from in depth interviews. To compensate slightly for this, new factors could be added in a free text space included after the listed items. Similar opportunities were given in most questions. Interviews would have given a richer description of how and why radiologists reason as they do, and provided a better understanding of their perspective. Hence, this would be a useful follow-up of the current study. The main reason for choosing a quantitative approach was to be able to single out the most significant factors (for each main question) according to the radiologists, providing valuable information for improving the utility of imaging.

4.1 Validity of the examination frequency study

The data format chosen for the examination frequency study gave almost complete, detailed and fairly uniform information. In our opinion, the chosen method was the best available for the purposes of a nationwide data collection with a reasonable use of resources, which is comparable with previous surveys and compatible with dose measures. Nevertheless, the study was not free from methodical challenges and validity questions. These will be addressed in the following, starting with some comments about overall uncertainty in the frequency estimates.

4.1.1 Overall uncertainty in frequency estimates

A multinational project involving 10 European countries made rough evaluations of accuracy of frequency estimates and subsequent patient doses, which included our study [45]. In the evaluation they included three important sources of uncertainty:

> "1. Errors in relating the information stored in terms of examination codes into actual numbers of examinations
> 2. Bias in the sample and inaccuracies in the scaling factors used to derive frequencies for the whole country
> 3. Lack of frequency data from some important providers of radiology services." [45, p. 95].

Here, inadequacies in the coding system were pointed out as the major cause of uncertainty in our study. Possible mismatches between number of times a code is recorded and the number of examination is a known problem in various coding systems, either due to too little or too much detail in the coding systems [45]. In our case, the latter situation was the challenge, which I will discuss below. The reason why overall uncertainty in our survey was still considered to be very low [54] was due to very small sampling errors and completeness of the survey [45]. The data material was free of bias resulting from small sample sizes, and no major providers were left out.

Uncertainty due to incompleteness of the data mainly concerns angiography examinations and PTCA (percutaneous transluminal coronary angioplasty), [55] because we might have missed some of them performed outside radiological departments [45]. Examples of other examinations not included for the same reason are ultrasound performed by gynaecologists and fluoroscopy in orthopaedic procedures. The scope of these activities is not known. For chiropractic use of radiology we have knowledge of the examination frequencies from a survey in 2005 [142]. This showed that 40% of the radiological examinations of chiropractic patients were performed within the chiropractic setting, and 60% were referred to hospitals or private radiological institutes. The frequency of examinations carried out in chiropractic settings was estimated to be 3 examinations per 1000 inhabitants, i.e. approximately 0.3% the total examination frequency reported here. However, these sources of incompleteness, and

[54] Uncertainty in the total frequency for all Top 20 Exams in Norway (i.e. the 20 examinations that contribute 70-90% of CED for all x-ray examination in the 10 involved countries) was calculated and found to be low compared to the corresponding figures for the surveys from the UK and Germany [45].

[55] The relative uncertainty for frequencies for these procedures was calculated to be 20%, while the uncertainty for other examinations varied between 2.5% and 5% [45].

accordingly underestimation of examination frequency, do not affect the trend analyses, since these data were not included in the previous surveys. [56]

4.1.2 Use of examination code to estimate examination frequency

The challenges that arose from estimating examination frequency from examination codes are most important, because these estimates form the basis of all subsequent analyses. NORAKO was new in 2002 and was not tested properly. One identified insufficiency was the possibility of coding one examination in different ways. For instance, it is possible to code examinations of bilateral organs twice (right and left, instead of both sides), which results in higher reimbursement [143]. [57] The possibility of increasing income by making efforts in the coding of examinations is documented [144]. For these reasons, the leader of the Norwegian Society of Radiology was critical about using NORAKO 2002 to estimate examination frequencies [145].

Without doubt, to measure number of examinations based on data on number of examination codes, implies a construct validity challenge, which we took into account and made adjustments in the data material – as far possible (as described in Section 2.1.1).

Inconsistencies in coding practice as observed in our analyses introduce potential biases in the examination frequency estimates. In the following, I will describe the most striking examples and assess the possible impact on the validity of the study.

Variation in the use location codes

NORAKO 2002 recommended the use of assembling codes when more than one anatomic region, organ or organ system was included in the same examination. The use of these codes varied between the institutions. Hence, the use of several single codes instead of assembling codes due to misinterpretation of the user manual, or for economic motives, cannot be ruled out. It was not possible to estimate the scope of such practice, but it is reasonable to assume that the problem is limited to some ultrasound examinations and angiographies/interventional procedures.

[56] Within the radiological institution, a source of incompleteness is examinations not refunded by the National Insurance Administration. One of the private radiological institutes informed us that they had not included such data, but that such examinations were very infrequent.
[57] This effect was dealt with in later versions of NORAKO.

Variation in the use of procedure codes

As mentioned in Section 2.1.1, the user manual was somewhat inconsistent by giving examples contradictory to the general recommendations. Hence, variation in coding practice could be expected. The use of codes for additional series for CT examinations varied greatly between institutions, 21% for private radiological institutes and between 2% and 5% for different kinds of hospital. These differences are not present for MRI examinations, though the use of additional series for MRI varied considerably between single institutions, from none up to 80%. However, these differences do not represent a major source of error, because we deleted most codes for additional series. Also, the procedure code intravenous contrast (IV) in CT was handled. The possibility that procedures have been coded in a separate string (double coding) in other cases cannot be ignored. However, the scope of this problem is limited. First, the use of other procedure codes was moderate. Second, such practice would have been visible with a consequent higher number of codes without procedure than with procedure. The latter was not observed, and we concluded that in this respect the institutions had largely interpreted the user manual correctly.

Variation in use of side codes

Regarding examinations coded as bilateral (*B*), we observed a tendency of even numbers, which indicate that some of the institutions may have counted these twice (i.e. multiplied each of these examinations by two). For mammography examination, it is likely that some institutions have coded each breast separately as right (*D*) and left (*S*) instead of correctly *B* when both breasts were examined during the same visit. The tendency of very few or no *B* codes and at the same time a high, and close to equal, number of *D* and *S* codes was observed most often for private radiological institutes, but also for some hospitals (see Table 4). Approximately half of the institutions that have used side codes for mammography seem to have minimized the use of *B* codes. If all these are cases of wrong coding (which we do not positively know) we should have reduced the number of mammographies by approximately 10%.

Table 4: The use of side codes in mammography by type of institution

Type of institution	Without side codes	Bilateral	Dexter	Sinister
Screening mammography	148526	-	-	-
Private hospital	913	-	-	-
Radiological institute	35326	24375	32077	32080
Public hospital	27209	7235	9240	8243
University hospital	4213	9724	4896	4999

Overall assessment

The adjustments made to derive the number of examinations from codes may have led to overestimation of number of examinations, while underestimation is less likely for two reasons. First, in the data preparation we were careful not to delete codes that could possibly represent an examination, while codes that possibly merely represented a description of the examination may have remained undetected. Second, a study by Espeland et al. [146] indicates that our examination frequencies are overestimated. Espeland et al. used number of claims for reimbursement from NAV (the Norwegian Labour and Welfare Organisation) to analyse utilization of ambulant MRI of the knee. Compared with our findings, their figures were 3% lower for public services, and 14% lower for private services. The difference of 14% cannot merely be explained by overestimation in our study due to procedure codes, because such codes only constitute 6.5% for this examination. An additional possible explanation is differences in coding practice e.g. for side codes (left and right instead of both sides), which may manifest itself differently in the two data materials. The difference indicates overestimation in our study, though some underestimation in the study of Espeland et al. is also possible, i.e. that some claims might be missing in the statistics.

4.1.3 Use of existing dose values for estimating CED

Fortunately, few of the coding difficulties are assumed to influence the dose estimates, either because the difficult procedures are infrequent [58] or because the way of counting fits with the way the dose values are given. [59] Most of our dose estimates are based on dose values measured nationally one or two decades ago, published in 1997 [57,136]. The uncertainty in

[58] E.g. angiography/interventional procedures, which are counted per organ instead of total examination, accounted for only 2% of all x-ray examinations.
[59] E.g. duplicate organs are counted without considering whether one or both sides were examined, and dose values were fittingly representing ‘average examinations’. Mammography was reported and analysed more accurately.

these data was estimated by taking into account uncertainties due to variation in patient doses between x-ray rooms and the limited number of rooms in the survey, and uncertainties in the coefficients used to convert the measured dose quantities into typical effective doses [45]. [60] The estimated uncertainty of effective dose for single examinations was typically 14% (estimated value for 11 of the included 20 examinations). [61] The highest uncertainty (51%) was estimated for cardiac angiography, PTCA and cervical spine examinations, and the uncertainty was also generally high (27%) for conventional examinations of the intestinal tract (with barium contrast media).

Since these measures were made, major technological developments have taken place, e.g. the introduction of digital detectors in plain radiography, multi-detector CT, tube current modulation (TCM) in CT etc. This has most likely affected the mean effective doses of single examinations, but the resulting influence on collective effective dose (CED) is uncertain. [62] In a follow-up study conducted by the Norwegian Radiation Protection Authority, dose data were collected between 2006 to 2008 and compared with mean effective doses used in our study [148]. This showed a decrease in doses from plain x-ray examinations, while the trend was less clear for more complex fluoroscopy procedures and angiography, for which both increase and decease of dose was found [ibid]. Most important regarding the validity of our study is the decrease in dose from CT examinations, because of the substantial contribution to collective effective dose. This indicates that the doses in our study are overestimated, given that these dose-savings were already present in 2002. The likelihood of this depends on the reasons for the dose reduction. Besides technological developments, professionals' dose optimization efforts are a significant factor for explaining dose reduction. It is likely that such measures escalated in the years after 2004 when a new regulation was implemented with increased demands for dose optimization, dose registration and use of diagnostic reference levels [149].

In 2007, the International Commission on Radiological Protection (ICRP) recommended modification of the tissue-weighting factors to use in estimation of mean effective doses [21].

[60] Uncertainty in conversion coefficients "depends on how closely the exposure conditions and the phantom for which the conversion coefficients were calculated match the average exposure conditions in the average patient for the x-ray examination in question" [45].
[61] Again the estimates included the Top 20 Examinations (see footnote 54).
[62] There are possibilities for dose reduction in new technology, for instance multi-detector CT, but whether the dose increases or decreases compared to single-detector-row CT depends on the scanning model and how it is operated [147].

The most marked changes were introduced for gonads (the weighting factor was reduced from 0.2 to 0.08) and breast (the weighting factor was increased from 0.05 to 0.12). Again, effective dose estimates of single examinations will be affected. A recent study by Huda and Magill showed that incorporating the new weighting factor in CT examination "increase the effective doses for head scans by ~ 11%, for chest scans by ~ 20%, and decrease the effective doses for pelvis scans by ~ 25%" [150]. This indicates a moderate effect on total CED in our study.

4.1.4 Use of location where examinations were performed to estimate geographic variation

Using activity data from institutions to estimate geographic variation represents an external validity challenge, even though we have taken care of this for the two large Oslo hospitals with nationwide function. Ideally, the scope of the migration problem should be assessed by comparing the results from studies using alternative methods for investigating the same questions. Unfortunately such studies for the whole range of examinations are not available, but the study mentioned above of a single examination (knee MRI) [146] can give an indication. When our county-based figures are merged into the same 5 geographical regions as used in the knee MRI study, [63] our data show the highest variation (see Figure 6). This means that use of MRI knee in the East region is probably overestimated in our study, and includes a fraction of patients from the South region. However, the pattern of variation is similar when using the two types of data material, with high numbers in the East region.

[63] Date for population statistics also had to be the same (we originally used population per 1/1 2003, while the comparing study used population per 1/1 2004).

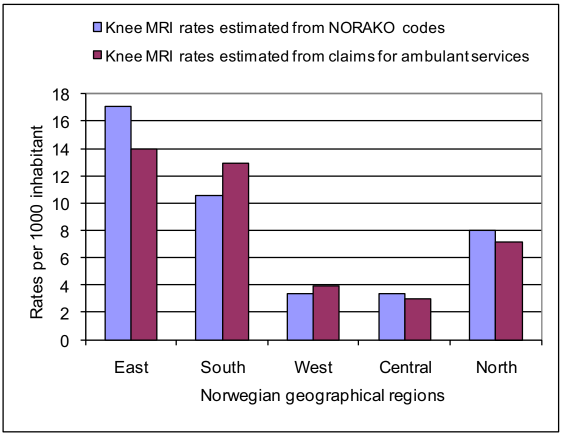

Figure 6: Rates (per 1000 persons) for knee MRI in Norwegian geographical regions in 2002 estimated from NORAKO codes versus claims for ambulant services.

However, this single examination may not be representative. The migration problem may be large in this examination, as patients receiving MRI of the knee are generally younger and relatively mobile (despite possible walking problems). Another study analysing reimbursement for all ambulant radiological services supports this suspicion: Dahl and Ellingsen found relatively little migration of patients between geographic regions (east, south, west, central and north) for public services [151]. For private radiology services, they also found an association between reimbursement rates in the regions and patient residency.

To use counties rather than health regions as the unit for analysis for estimating variation can be better for reflecting the characteristics of the geographical regions relevant for utilization of radiological examinations. On the other hand, using smaller units increases the validity problem of migration between neighbouring counties with small areas and high population density. In these cases, accessibility is high, which partly explains the high examination rates in Oslo compared to the neighbouring county of Akershus. However, the examination frequency is high in the East region as a whole.

4.1.5 Statistical validity

The risk of *type I* errors (obtaining statically significant results when the null hypothesis of no association or effect is true, a 'false positive') was present when the hypotheses in Article II were tested, because multiple tests were conducted (except for the hypothesis that private institutions contribute to geographical variation in examination frequency). Bonferroni correction is a method for reducing the risk of *type I* errors in such cases [152]. [64] However, there is “no formal consensus for when Bonferroni procedures should be used, even among statisticians” [152], and the issue is a subject of discussion [152-154]. A serious problem is that a Bonferroni correction increases the risk of *type II* errors (i.e. to accept an incorrect null hypothesis) [152]. [65] For this reason, Bonferroni correction is considered too strict when a large number of comparisons is preformed [139]. This was the case in our hypotheses about correlations between the counties’ use of different modalities for examination of the same specific organs, where testing of a total of 24 correlation coefficients implies an adjusted level of significance of 0.0021. The high probability of *type II* errors is grave, particularly because of the exploratory aim and pilot nature of the study. Bonferroni corrections can be omitted in pilot studies (personal conference with statistician M.C. Småstuen). Therefore we chose to present the p-values as computed without any adjustments and considered p-values <0.05 as significant. However, it is important to interpret our results with caution and as indications, pending confirmation in prospective studies.

4.2 Validity of the radiologist studies

The validity questions of special concern in the radiologist survey were related to questionnaire content, representativity, and statistics.

4.2.1 Questionnaire content

The process of constructing the questionnaire is explained in Section 2.2.2, including efforts to obtain content validity. Content validity (also called face validity) should be tested by experts or representative subjects, albeit using subjective judgement [140]. This advice was followed, and contributions from individuals and a group of radiologists led to substantial improvements of the questionnaire, regarding number, order and wording of the questions/items. After the pilot study, the questionnaire was revised further, but only slightly.

[64] Bonferroni correction is a conservative method, in which the level of significance is adjusted by dividing the *P* value by the number of variables being analysed [152,153].
[65] A wide use of Bonferroni procedures may also contribute to publication bias, “because presentation of more tests with nonsignificant results may make previously ‘significant’ results ‘nonsignificant’ under Bonferroni procedures” [152].

A second pilot study could have been used to investigate the reliability of the questionnaire by test-retest analyses. However, this would have required person-identifying labels, which we decided to avoid. [66] Furthermore, we assessed the pilot responses as generally thorough with few missing values and good utilization of the response categories. [67] This suggests that the questions were well understood and regarded as relevant. Also, few missing responses in the main survey contribute to the internal validity of the studies.

The questionnaire consisted of lists of single items for each question. Whether these lists were complete was a major concern in the process of constructing the questionnaire. Particularly, it could be argued that the list of causes of unnecessary investigations (Question 2) should have been extended (which one journal's reviewer suggested). For instance, some of the causes suggested for increased investigation volume (Question 1) could also have been relevant causes of unnecessary investigations. [68] There were three reasons why we decided to keep to the main causes as stated in Referral Guidelines for Imaging [113]. First, these six listed causes are more like a classification of unnecessary investigations than descriptions of the underlying motives of the stakeholders. Hence, radiologists should be better able to assess them. Second, contrary to the chosen list, opinions may vary about whether some of the "missing" causes are warrantable, like competition for patients and risk of litigation. Disagreement on the questions (whether the phenomenon actually causes unnecessary investigations) could cause bias. Third, quite a few of the "missing" causes are probably covered by the wide last item: over-investigation (because some clinicians tend to rely on investigations more than others and some patients take comfort in being investigated).

Unfortunately, the questionnaire items could not be correlated with objective measures or accepted standard measures (criteria validity assessment), as such data do not exist. Hence, we cannot claim, for instance, that the radiologists' self-reported actions when confronted with inadequate referrals (Article IV) correlate completely with how they actually act. There

[66] Dillman recommends the use of identification numbers on each questionnaire so that follow-up mailing can be sent only to non-respondents, and says that this "seems not to have a serious negative effect on response rates" [138]. We prioritized response rate, accepting the inconvenience of reminders to the total sample.
[67] 14 of the 20 invited pilot radiologists replied, and one radiologist informed us that he had not responded because he had retired. The questions included in the articles (1, 2, 5, 6 and 7) consist of 46 single items, of which only three had missing values (only one each).
[68] According to Levin and Rao, self-referral is the main cause of over-utilization of imaging, followed by defensive medicine (fear of malpractice liability), repeat examinations due to low quality of initial examinations, and lack of knowledge of the referrers [66]. The importance of self-referral in the USA would not be valid in Norway, where the vast majority of referrals are from a non-radiologist to a radiologist in a radiology department or institute.

is always a risk that the answers may be influenced by the perceived justifiability of the items (in all questions), resulting in biased data. The study design should mitigate the tendency to give answers that make the respondents themselves "look good" [140]. Two conditions may have countered embellishing of replies. First, there is no norm regarding "appropriate replies". This argument is most relevant for the question about actions against inadequate referrals. There is no norm describing how frequent radiologists ought to act; this also depends on the frequency of inadequate referrals, which is unknown. Second, we assumed that omitting person-identifying labels on the questionnaires would make embellishing unlikely.

Radiologists' perception and assessment were regarded as most relevant for our purposes, although other methods could have provided more numerically precise information, e.g. observations of how often the radiologists act against inadequate referrals and how often unnecessary investigations occur. These questions are measurable, though not easily. However, we were most interested in the relative importance of the different factors that influence utilization, because the aim was to identify the potential for improving the use of radiological services, in particular through the efforts of radiologists.

An illustration of the usefulness of the approach (despite suboptimal precision of measurement) is given in the questions asking the radiologists to grade the contribution of factors preventing and not preventing an examination of doubtful usefulness from being performed (Questions 6 and 7). Their answers to these questions may reflect how often the factors actually occur, not only to what extent they would contribute to a decision when they occur. For example, when 'the radiographer questions the referral' was rated low, this may be because radiographers rarely question the referral, or because their questioning is not a highly valued factor in the radiologists' decision-making process. Irrespective of which interpretation is correct, the finding clearly indicates that radiographers do not contribute much to radiologists preventing examinations of doubtful usefulness.

4.2.2 Representativity

The aim was that the study results should be valid for Norwegian radiologists. By using the list of NMA members, we assume that almost all radiologists were included, as most physicians are members of the NMA [137]. The exact number of radiologists is not known, but there is no reason to believe that the proportion of radiologists who are NMA members differs from physicians in general. We also achieved a fairly high response rate of 70%. [69] These features contribute to the external validity of the studies.

The reason for being somewhat cautious about generalizing to the population of Norwegian physicians working in radiology is the underrepresentation of physicians who are not yet approved radiologists (registrars). The fraction of registrars was 17%, both in the sample and in the group of respondents (see Table 5), which indicates representativeness of the data. Unfortunately, the sample does not include more than about 50% of the registrars due to missing affiliation information for these members by the NMA (A. Taraldset, NMA, personal information). This corresponds with figures reported for 2006, where 29% of positions in radiology were held by registrars [156]. The overrepresentation of approved specialists implies that privately employed radiologists are also somewhat overrepresented, as registrars only work and are trained in hospitals. The extent of the overrepresentation is approximately 3 percentage points compared to the figures from Heldaas et al. [156].

Table 5: Characteristics of respondents, total selection and radiology staff in 2006[1]

	Respondents[2] n (%)	Total selection[3] n (%)	Radiology staff in 2006[1] n (%)
Gender			
Female	161 (42.9)	231 (41.0)	
Male	214 (57.1)	333 (59.0)	
Specialist / registrar			
Specialist	312 (83.2)	469 (83.2)	461 (71.5)
Registrar	63 (16.8)	95 (16.8)	184 (28.5)
Hospital / institute employed			
Public	311 (88.9)	515 (91.3)	599 (92.9)
Institute	39 (11.1)	49 (8.7)	46 (7.1)

[1] The figures about radiology staff in 2006 were given in a report by Heldaas et al. [156].
[2] The total number is 350 (25 less) in the hospital / institute employed variable due to missing values.
[3] The number of 49 institute radiologists was provided by A. Taraldset, NMA (personal information) based on registered age (below 70 years), practising (yes) and workplace classification (private radiology).

What are the possible implications of this slight selection bias? Regarding causes of increased investigation volume (Article III), we found that specialists scored higher on the latent variable *medical possibilities* than registrars. Analysing the two groups separately showed that

[69] According to a study by Cook et al. the mean response rate in postal surveys of doctors is 57.5% [155].

they rank the single items (from which the latent variables are derived) almost equally, [70] but the mean values for registrars were generally lower. Hence, more registrars among respondents would probably not have influenced our finding, because our main interest was the relative impact of the factor (not the size of the scores). However, for the other main question in Article III (about causes of unnecessary investigations), a more representative selection would probably have strengthened our findings of over-utilization and insufficient referral information as the main causes of unnecessary investigations. Regarding radiologists' actions in response to inadequate referrals (Article IV), our reported frequencies of action may also be slightly underestimated due to selection bias.

Certainly, we cannot generalize our findings from our Norwegian sample to radiologists in general. This does not mean that our findings have no transfer value outside the context of Norwegian radiologists in 2007. Stakeholders abroad may find the study results relevant, due to similarities in utilization pattern of imaging and the radiologists' role in making decisions about examinations, as well as general trends in international radiology, such as developments in technology. The findings may be particularly interesting in the Nordic countries, because of common features in health care policy [55].

4.2.3 Analyses and statistical validity

In the articles, the five-point scale (to a very small extent, to a small extent, to some extent, to a large extent, to a very large extent) was re-coded into a three-point scale to ease the interpretation and presentation of the distribution of responses. By combining the two responses at each end of the scale, some information is lost. However, in general the respondents tended to avoid the extreme categories (to a very small extent and to a very large extent). [71] Chi-square tests were applied to test for possible associations among subgroups of respondents. It is recommended to combine reply categories of variables to avoid too many

[70] The latent variable *medical possibilities* consists of *increased possibilities due to new radiological technology,* which was ranked highest in both groups, and *expanded clinical indications for radiology,* which was ranked number 4 among specialists and 5 among registrars.

[71] The exceptions are found in the questions about factors that affect radiologists' decision to prevent (Question 6) and not prevent (Question 7) an examination of doubtful usefulness. In Question 6, the item *high risk of serious complications or side effects* 'to a very large extent' received twice as many responses as 'to a large extent' (201 versus 103). In Question 7, the item *high reimbursement rate for the examination* 'to a very small extent' received more than threefold as many responses as 'to a small extent' (255 versus 81). For a few other items the frequencies of responses falling into the extreme and the moderate response categories were almost equal.

cells with too small number of expected observations [139]. [72] Hence, additional re-coding was performed and the previously four-point scale (daily, weekly, monthly and less frequently than monthly) was dichotomized into the categories 'daily or weekly' and 'monthly or less frequent than monthly'. The neighbouring categories of the original five and four scales were considered to be similar, so we did not expect much information to be lost when the scales were re-coded and simplified.

When comparing replies between subgroup of respondents, multiple tests were performed. Subsequently, the risk of *type I* errors is also present in this study. The argument for not applying Bonferroni correction is that this study could also be considered a pilot study (see Section 4.1.5), because previous similar research is lacking. The risk of reporting a spurious association should be high when exploring the association between specialists/registrars and hospital/institute radiologists regarding factors contributing to examination being prevented or not (Questions 6 and 7). However, despite many tests (19 items and 2 independent variables) we found only six statistically significant associations. Also regarding the five latent variables (Article III), we found few associations with demographic, professional and practice setting characteristics. This suggests a possible opposite problem: have we failed to observe possible small differences between groups of respondents (*type II* errors) because of small sample size? Some of the subgroups consist of few respondents, e.g. only 39 institute employed radiologists. Increasing the statistical power by having a larger sample was considered to be difficult, as we used the membership list from the Norwegian Medical Association, which included almost all possible respondents. [73]

[72] It is recommended that "80% of the cells in the table should have expected frequencies greater than 5, and that all cells should have expected frequencies greater than 1" [139].
[73] For this reason we did not calculate Statistical Power. Statistical Power is defined as $100(1-\beta)\%$, where β is the probability of a Type II error. Apart from the sample size, the value depends on the size of the effect one is going to measure [139]. Our sample could have been increased had we included more registrars, but these were considered only reachable through exhaustive methods.

5 NORMATIVE DISCUSSION

This dissertation is based on empirical studies of different aspects of utilization of diagnostic imaging. In the introduction, I argued that such research is ethically relevant for a number of reasons. This means that the study findings could have been discussed normatively within many ethical perspectives, e.g. distributive justice and priority setting, professional ethics and responsibility. One reason why I regard the utilitarian perspective especially relevant is that the common underlying themes for all the articles are the issues of excessive utilization and the utility of radiological services (additional reasons are given in Section 1.6.5). The thought is that empirical research findings can provide useful information for considering and discussing the issue of utility of imaging services. The two main questions that will be addressed are: What is the utility of increased use of imaging (Section 5.1), and what is the utility of different norms and measures (existing and suggested) to influence or manage utilization (Section 5.2).

5.1 Increased utilization of imaging and utility considerations

One central finding in this project is the conspicuous increase in utilization of the new technologies MRI and CT (Article I). Our latest data were collected for the year 2002, but according to more recent studies, this trend seems to be continuing in Norway. Almen et al. report a factor 2 increase in the use of CT and MRI examinations from 2002 to 2008 [148]. Espeland et al. investigated utilization of MRI of the knee, and reported a 64% increase (in claims for reimbursement of ambulant examinations per 1000 persons) from 2002 to 2004 [146]. The growth in volume of ambulant radiology from 2002 to 2006 was estimated to be 39% for public services and 123% for private services, according to a report from the Norwegian Labour and Welfare Organization [151]. Corresponding findings [43] indicate a general trend in developed countries towards a continuing increase in utilization of high technology imaging.

From a utilitarian point of view, the question is whether the increase in use of high technology imaging is useful, i.e. does it benefit the patients receiving the services and society at large? This question of outcome of increased imaging has at least three dimensions: 1) Does increased use lead to improved health for the population or subgroups of the population? 2)

Does increased use lead to less pain? 3) Does increased use lead to lower costs for society? These questions will be discussed in turn in the three subsequent sections.

5.1.1 Does increased use of imaging improve health outcome?

There are empirical data that support different answers to the question of health outcome. In this section, I will show how the empirical data support each of the answers: a) yes, increased use of imaging does improve the health outcome for patients, b) perhaps, such benefits can be provided, but we lack knowledge about the health outcome of new technologies and c) no, improved health outcome for the patients receiving the examinations cannot be expected. I will then discuss the possible extent of improved health outcome from increased utilization of imaging, drawing on the concept of marginal utility.

To the public, the *yes* answer may seem obvious, because it is counter-intuitive to people that such high-tech, modern medicine might not be useful [157]. This anticipated usefulness is probably due to a general belief that application of new technology will improve the *quality* of health care services [158]. The professionals' major argument why increased imaging promotes patients' health is that new technology makes it possible to detect disease more accurately and at an earlier stage [5]. Radiological technology can then guide choice of treatment better (initially and continuing), and detection of disease in an earlier stage makes less invasive treatment possible. Consequently, morbidity and mortality can be reduced. In this way, subgroups of patients can clearly achieve health benefit from growth in the use of imaging.

Our findings indicate that radiologists largely consider increased use of imaging as beneficial. This is assumed because 'medical possibilities through new technology' and 'expanded clinical indications for radiology' were rated high among causes of increasing examination volume (number one and four respectively) (Article III). These two causes (combined in the latent variable *medical possibilities*) correlated negatively with all causes of unnecessary investigation. This means that, according to the radiologists, medical possibilities are a major reason for increased use of imaging, and this is not at all associated with unnecessary investigations. On the other hand, the radiologists' emphasis on medical possibilities may not reflect perceived improved health outcome, but rather utility at a lower level [74] i.e. the examinations' ability to provide appropriate diagnosis (diagnostic thinking efficacy) or to influence patient management (therapeutic efficacy) [159]. After all, radiologists are not in the best position for getting information about the final health outcome of the examinations.

The *perhaps* answer means that we lack knowledge about the health outcome of the new technology that is increasingly utilized. The documentation requirements, with proper evaluation of usefulness and optimal application, are challenged by the rapidity of technological development [15,160,161]: "In fact, new imaging technologies are often implemented as soon as they are available, on the basis of subjective experience with a limited number of cases" [161]. Hence, we do not know whether the new technology will produce higher quality services or benefit patient care [51]. This (too) early diffusion of new technology is driven by physicians' desire to improve practice, supported by anecdotal evidence, though the industry and manufacturers often provide the initial impetus for "getting the ball rolling" [162]. More indications for CT are e.g. said to be largely driven by "better and faster machines combined with innovative scanning protocols and post-processing techniques" [69]. In addition, consumer [75] demands may play a role if driven by direct-to-consumer advertising [162].

Premature implementation also weakens the chance of providing high quality evidence, i.e. to gain knowledge about the utility of the technology, as in the case of screening tests [128]. [76] However, the demand for documentation should not become too rigid, as we than risk patients being deprived of highly useful examinations while we wait for solid documentation [128]. It is difficult to know when the documentation is sufficient, and professionals will always have to use discretionary power and consider whether the documentation of usefulness is sufficient to offer the technology to individual patients.

[74] The levels refer to a six-tiered hierarchical model presented by Fryback and Thornbury on the efficacy of diagnostic imaging [159]. The most micro (local) viewpoint describes technical quality of images (level 1), and the most global describes societal costs and benefits (level 6). In between we find diagnostic accuracy (level 2), impact on diagnostic thinking (level 3), effects on patient management (level 4) and patient outcome (level 5).
[75] The concept *consumer* is (so far?) unfamiliar in the Norwegian health service context.
[76] I see individual requested screening as one, and perhaps an "archetypical", source of over-utilization of imaging. Individual requested screening can be defined as: "those [examinations] which have not been recommended at the population level, but which are nonetheless sought by patients or offered by physicians on an ad-hoc basis when either party is concerned about latent disease and believes that early detection may provide life-saving benefits" [128]. Examination in order to uncover unsuspected disease and periodic examinations of healthy subjects was reported to be a major cause of wasted x-ray as early as in the 1970s, ironically described by the car allegory with concepts like 'thorough overhaul', 'complete check-up' and 'physical decarbonisation' [12].

Lack of documented knowledge of utility is not restricted to new technologies. There is a general deficit of studies of efficacy, effectiveness and efficiency [77] of radiology services. Particularly, high level efficacy studies (patient outcome and societal costs and benefits) have been lacking [159]. However, lately we have seen some studies designed to investigate the usefulness of imaging examinations on a population level, for instance focusing on routine chest radiographs [164], CT pulmonary embolism mortality [165], MRI knee [166] or broadly investigating a range of procedures [167]. The number of cost-effectiveness analyses is increasing rapidly, but these studies are still burdened with methodological problems [168].

The answer *no* – that (a fraction of the) increased use of imaging will not improve health outcome – is supported by several empirical findings. In Article I, we pointed out that the overall increase seems to be unrelated to the medical status of the population, which had been fairly stable in the period. [78] Correspondingly, the radiologists rated morbidity in the population lowest of all causes of increased examination volume (Article III).

Moreover, some findings indicate that the increased use of imaging is partly futile. For instance, the radiologists rated the referring physicians' reduced tolerance of uncertainties high among the factors of increased utilization and (in turn) the latent variable *referring physicians' uncertainly* [79] was associated with high ratings of unnecessary investigations (Article III). The impact of uncertainty is supported by studies of referring physicians' own perceptions [53,169,170]. Furthermore, one half of the radiologists reported that unnecessary investigations occurred to a large or very large extent in their own workplace due to 'over-investigation, because some clinicians tend to rely on investigations more than others and some patients take comfort in being investigated' (Article III). Other studies report substantial fractions of non-contributive examinations. In a CT department, 37.6% did not (and 22% did partly) alter the therapeutic planning [171]. In a study of 1153 primary care referrals, 87% of knee examinations did not lead to management change [172]. None of these findings proves that the proportion of wasteful examinations increases with increasing utilization. However, it

[77] Haynes differentiates between these related concepts in the following way "Efficacy in the extent to which an intervention does more good than harm under ideal circumstances ("Can it work?"). Effectiveness assesses whether an intervention does more good than harm when provided under usual circumstances of healthcare practice ("Does it work in practice?"). Efficiency measures the effect of an intervention in relation to the resources it consumes ("Is it worth it?")."[163]

[78] The geographical variation in utilization seemed also unrelated to health conditions (Article II).

[79] Including the three factors: less tolerance for uncertainty by the referring physicians, less knowledge of accurate use of radiology and less competence to perform clinical examinations.

is reasonable to assume that the number of wasteful examinations increases at least correspondingly with the number of examinations.

Marginal utility

The most interesting questions are perhaps to what *extent* increased utilization of imaging brings about health gains, and to what extent we risk that more examinations will not improve health outcome. Marginal utility is a useful concept when addressing this question. Here I will argue that the health gained by increasing utilization plausibly follows an "ordinary" diminishing slope of marginal utility (see Figure 4, page 18). This means that we should expect less health benefits from each step of increased use of imaging, and a tipping point beyond which utility becomes negative, i.e. a level of utilization where additional imaging will do more harm than good. A principal explanation is that the risks of harm from each examination are constant, while the benefits decrease when the health situation in the population is stable. One of the risks may in fact increase with utilization level. If we examine more people without disease, the risk of false positive results will increase, because the proportion of false positive results is higher relatively to true positive results when the prevalence of disease in the tested population is low [83]. The test's positive predictive value can therefore decrease with increased utilization.

On a practical level, the problem is that we do not have any evidence-based benchmarks to help us to assess whether the level of utilization is appropriate [36]. Neither do we know where this tipping point is, nor where on the marginal utility curve current utilization might be. Some empirical findings indicate that we have reached a level where the additional utility of increased utilization may be limited. First, new technologies tend to supplement rather than replace existing techniques (Articles I and II). This is supported by other empirical research: "…evidence does not suggest that MRI availability offsets CT use but rather seems to suggest the opposite" [51]. This indicates that some patients receive more examinations for the same condition, due to the relatively stable health conditions in the population. More examinations may be very useful in a single case, as in questions of differential diagnosis. However, this may also reflect the thinking that "more tests yielding the same findings increase confidence in the diagnosis" [161]. [80] This leads to decreasing marginal utility on an individual level. The

[80] Other reasons for supplementary rather than replacing examinations are traditional referral behaviour, and low accessibility of the newer technologies, e.g. the patient receives a plain x-ray while waiting for a more appropriate MRI. In either case the utility can be questioned.

first examination that provides a diagnosis is very useful. To confirm this diagnosis with a second (perhaps more advanced) examination can be useful, but less than the first. Further confirming examinations will soon become futile.

A second indication of decreasing marginal utility is found in the study of geographical variation in examination frequency (Article II). Certainly, we should not ignore the possibility of too low utilization in rural areas, but the findings do not point in this direction. The highest variation was found in examinations for which the appropriateness has been questioned, and which are not usually requested to reveal the most serious diseases (e.g. knee and spine) (Article II). This suggests a sufficient overall level of radiological services, and that the higher use rates in urban areas may yield little to improve health outcome. Other researchers have investigated the effect of health care spending (including frequency of tests) and found no evidence of "improved survival, slower decline in functional status, or improved satisfaction with care" in higher-spending regions [28].

In summary, empirical findings suggest that the health gained by increased use of imaging might not be as comprehensive as one immediately would assume. However, it is argued that we are using the wrong measures for detecting the benefits of imaging, "measured so coarsely, largely as deaths or severe morbidity, while imaging will often affect the quality more that the length of life, by reducing pain and anxiety, shortening hospital stays, and reducing the time to fully functional recovery" [173]. Accordingly, we should look for such benefits.

5.1.2 Does increased use of imaging decrease pain?

A second option is that increased use of imaging is useful because it leads to less physical or mental pain. The newer imaging technologies have offered services that are less *physically* painful by replacing some investigations that inflicted pain directly or through being very tedious, e.g. air encephalography, lymphangiography and myelography. [81] Such examinations have now largely been replaced by CT and MRI scans. It is reasonable that less painful examinations lead to increased utilization, but less obvious that more imaging should lead to

[81] Air encephalography, lymphangiography and myelography are examinations of the ventricular system of the brain, the lymphatic system and the spinal canal, respectively, with injections of negative (air or other gases) or positive contrast media (oily or water-soluble).

less pain. The latter is true if imaging replaces painful medical procedures other than radiological procedures.

There are cases where the newer imaging technologies can contribute to less painful medical services, both diagnostically and therapeutically. For instance, exploratory surgery has largely disappeared thanks to imaging technology [5]. Less invasive therapies are possible by using fluoroscopy-guided procedures, and these replace an increasing number of traditional open surgical procedures [5]. Moreover, less physical pain can be achieved by avoiding further treatment, e.g. initial use of CT can avoid surgery for appendicitis in patients who turn out not to have the condition [5]. In this way, increased use of imaging can provide less invasive and less painful medical services, though relatively few patients (compared to the total number of patients receiving imaging procedures) can benefit from these rather advanced applications. Our findings show that "simpler" examinations still constitute the vast majority, and the steepest slope of increased use is found for MRI of the extremities, followed by MRI of the spinal column (Article I).

It is also argued that imaging is an effective means of reducing *mental* pain. Radiology is frequently used to reassure and comfort worried patients [53,174,175]. This phenomenon is wittily labelled "photon poultice" [12]. One of our findings supports that imaging for such comforting purposes does influence utilization: peoples' increased demands for certain knowledge about their own health was rated by radiologists as the second most important factor to explain increased investigation volume (Article III). The possible utility of imaging for comforting purposes can be used as an argument for liberal use of imaging, while such practice is considered wasteful from a restrictive perspective [113]. Utilitarian arguments can be used in both cases, by referring to the overall utility of reducing mental pain, and by questioning such utility and emphasizing the risks and cost. However, the latter position may also reflect non-consequentialist reasoning: that it is not right to use diagnostic imaging for such purposes even if doing so would provide the best overall outcome. After all, radiology was not developed with the purpose of being a remedy for mental worry [176].

Reduction of mental pain is expected by giving the patient relief of anxiety for serious disease. Furthermore, some comfort (or peace in mind) may be achieved by providing an explanation of the pain or affliction, even if no treatment is or can be offered. Finally, to receive a referral for imaging may in itself comfort the patient, because this signals that the physician takes the patient's affliction seriously and gives him or her emotional support [54]. A physician's typical reasoning about the issue may be as follows:

> "When a patient presents with a perceived physical complaint and feels that radiography will help to allay his or her fears regarding this complaint, I am sometimes tempted to request radiography, knowing full well that the likely result is going to be negative. However, this may well be of considerable benefit in terms of reduced anxiety, improved perception of health and fewer consultations on the part of the patients, and less prescribing by the doctor." [175].

This quotation illustrates that the physician, despite the apparent benefits of 'therapeutic' x-rays, is somehow ambivalent: he is 'tempted' and later he indicates that such practice is something one does not like to admit. He might perceive that this deviates from evidence-based practice. There may be good reasons for this ambivalence from a utilitarian perspective. Utilitarianism would recommend 'therapeutic' x-rays only if it is proved or likely that such consequences would actually occur. Research indicates that the reassuring and comforting effects are anecdotal or exaggerated [177-180]. The widely held assumption that a reassuring effect can be achieved just by explaining that the test did not show any abnormalities has been refuted: Patients with symptoms are often left with anxiety despite normal test results [177,180]. Such benefits are also reported to be short term, e.g. for patients with chronic headache offered an MRI scan, the reassurance effect was present for some months, but then disappeared [178]. The decision to order radiological investigation may also *cause* fear of serious illness in some patients, and clinically insignificant findings may lead to uncertainty or preserve illness [53]. Knowledge of imaging finding is sometimes associated with a lesser sense of well-being, e.g. in patients with acute low back pain and/or radiculopathy receiving MRI [179]. Thus, examinations for comforting purposes can act as placebos, but can also cause nocebo responses (subjective worsening of symptoms).

It can be questioned whether increased use of imaging benefits patients by relieving them of anxiety, but what about the referring physicians? Our study showed that less tolerance for uncertainty by the referring physicians was a major factor in explaining increased utilization. Other empirical studies have shown that referring a patient for radiology gives relief to the physician when he is uncertain about his own skills in clinical examination, is anxious for missing important findings, or fears malpractice litigation [53,174]. This is highly understandable, and the expected reassurance effect will probably occur. However, the long term consequences may be less beneficial. The physicians' professional integrity and physician-patient relationship may suffer because the practice is somehow deceptive, exaggerating the medical utility of the examination. The consequences of following the rule of telling the truth would probably be better for the physician-patient relationship. Another possible adverse long-term consequence, when the purpose of the examination is purely to comfort the patients, is distrust. Patients may lose their trust in a physician if they become aware that their wishes for imaging have been met, but professional assessment has been disregarded.

It is also a part of the picture that pain – widely conceived, can be induced by increased utilization of imaging. False positive findings, incidentalomas and iatrogenic pseudodisease do not only represent a threat to patients' health, [82] but can also lead to anxiety and physical pain from unnecessary follow up investigations and treatment (see Section 1.8.4). However, studies in screening contexts have shown that people overestimate the benefits, have a poor understanding of pseudo-disease, and are quite tolerant of false positive results [128]. Perhaps more surprising is the so called "health certificate effect" from screening services, i.e. a negative test result gives a feeling of good health and "a sense of being taken care of by screening services [that] could reduce the incentives to take personal responsibility for a healthy lifestyle" [181]. Generally it seems that reduction in physical pain from increased use of imaging may occur in a limited group of patients, while reduction in mental pain is more uncertain. If any reassurance or comforting effects occur, it seems to be immediate rather than a long-term benefit, both to the patients and the physicians.

5.1.3 Does increased use of imaging lower the costs for society?

It has been argued that the rapid growth in the use of imaging has caused a biased awareness of the costs, while the steep growth curve may simply reflect beneficial and cost-effective services [5]. To realise this, we need more data of how imaging can reduce overall costs of care and we need to assess the costs in a wider context [5].

Many of the ways increased use of imaging can reduce health care expenditure have already been indicated. The ways health outcome can be improved, and pain reduced, are also in most cases cost-effective alternatives, e.g. the cost-saving effect of avoiding further treatment [5].

[82] Certainly, all health risks from increased use of imaging, e.g. risks of cancer from increased radiation doses (Article I), can involve both physical and mental suffering.

As explained by Otero, we can achieve: "lower treatment costs because of early diagnosis; reductions in unnecessary surgical interventions, hospital days, and per patient costs; the use of less invasive procedures, with faster recovery times; and more rapid and accurate diagnoses" [15]. Early admission is emphasized, because it is thought to reduce the number of physician consultations and limit the period of sickness benefit [62]. These effects are also thought to explain the financial benefits of 'therapeutic' x-rays [175].

Improved health outcome and decreased pain could by itself be cost-effective, as sickness and work disability are expensive to society. Hence, underuse of imaging may have a negative impact both clinically and economically [15]. However, in some instances the increased utilization of imaging seems to reflect that societal cost-savings have taken precedence over utility to individual patients. Economic pressure has been reported to be a major reason for performing repeat examinations [182]. Economic benefits were also the major reason for recommending replacing 24 hours observation in hospital by a CT scan in patients with concussion of the brain, while the suggestion was criticized for underestimating the radiation risk for children [183]. A CT scan of the brain was estimated to cost 30% less than 24 hours observation in hospital [183].

Most radiological tests are rapid to perform, read and report, so staff expenses are relatively low. But the service makes use of advanced high-cost equipment. Consequently, the *opportunity costs* (i.e. the value of alternative choices) of increased utilization of imaging may still be relatively high. I have argued that increased utilization partly serves patients without the most serious diseases. This calls for assessment of opportunity costs both within and beyond radiological services. Liberal access to imaging for patients with less severe conditions can cause queues of patients and displace examinations that would have been more useful. Hence, liberal access to imaging entails a risk of violating the egalitarian principle of utilitarianism (see Section 1.6.2). Paradoxically, today access to MRI is limited in Norway, while at the same time a vast number of knee MRIs are claimed to be futile [184].

It is not wrong from a utilitarian perspective to give priority to relatively healthy patients, if they can make better use of the services [87]. As explained (in Section 1.6.5), distributive justice has no intrinsic value in utilitarianism, and can be set aside if it does not promote maximum overall utility [89]. Nevertheless, we can assume that some of the resources used to increase radiology services could have provided more health benefit if used in alternative health care services. This is because of the uncertain ability of the examinations to improve health and reduce pain. There should be no need to repeat the many indications of confined utility of increased use, based on our empirical data and the empirical data of others. The challenge of unnecessary imaging is pressing, as it "sucks resources out of the health care system to no net benefit of patients or society." [5]. The MRI knee example is interesting, because it illustrates how important utility, in the shape of appropriate indications, is for cost considerations. Based on a Norwegian study, some have argued that 75% of knee MRIs could be considered to be futile (amounting to NOK 50 million a year) and that clinical examinations and plain x-rays would have been more appropriate [184]. However, for patients with knee injuries considered substantial enough to justify diagnostic arthroscopy, MRI examination was reported to be cost-effective (a study by Ruwe et al. quoted by Rogers [65]).

In summary, empirical findings partly support and partly reject the utility of increased utilization of imaging. There are indications of benefits and lack of benefits within all three dimensions of utility: improved health, less pain and lower costs. However, the overall utility of increasing utilization seems to be limited. Even if the beneficial value of increased utilization may be high in a fraction of the services, the findings indicate that the number of people who get this benefit is small relative to the number of cases where imaging may be futile and possibly harmful. The consequences of over-utilization (the risk of harm and the costs) may accordingly be more extensive and outweigh the benefits of cases where increased utilization is clearly useful. Hence, it is important to focus on utilization that is not clearly useful, and to question the utility of the different approaches to manage utilization of diagnostic imaging.

5.2 The utility of norms to manage utilization of imaging

A series of norms, measures and rules influence (or aims to influence) utilization of imaging. [83] Some of these, like clinical guidelines, explicitly aim to influence whether a patient should have an examination, which examination, and when and by what means. Others have a more indirect influence, like governmental health care policy and the reimbursement system. These different norms are not mutually exclusive; rather they complement each other, e.g. clinical

[83] *Norms* is used here as a general and overarching term for more specific action-guiding *rules* and specific *measures* given by e.g. the professional bodies or the policy makers. These concepts have in common that they give directions for decisions, actions etc. In this case, all the norms, rules and measures aim at influencing decisions and actions by the practitioners and the practice of diagnostic imaging.

guidelines can be an important tool in the process of vetting referrals. The norms have different primary goals: to protect the population against radiation, to provide appropriate services and to reduce costs. However, all the norms probably endorse avoiding overuse, and promote quality imaging in a cost-effective manner. From a utilitarian perspective, the value of these norms depends on their ability to promote such good consequences. The question is how useful these norms are (or can become) to manage utilization of imaging. As stated in Section 2.3 (referring to Hare's level 2), it is important to access critically the expected consequences of accepting and following the various norms, rules and measures. This is the topic for this section. [84]

Traditional approaches to utilization management address health policy makers, patients and in particular referring physicians. However, it should be evident from the Introduction that the radiologists have an important alternative and/or additional role, so far underrated. Therefore, in the discussion of the exciting and suggested norms and measures to manage utilization, I will emphasize the perspective of the radiologist. A main reason for this is that radiologists are knowledgeable about utility and the risks of imaging. This is valuable with regard to appropriateness of services and radiation protection. We cannot expect either the referring physicians or the patients to have equally updated knowledge as radiologists. Besides, the patient and the physician may be less responsive to risks, because they very much want the examination to be carried out. [85] Hence, the suggested strategy to curb over-utilization by increasing doctors' and patients' awareness of the radiation risk [71] is at best unrealistic. [86] Radiologists also have a professional interest in refraining from carrying out futile examinations, grounded in legal medical exception, which requires actions according to professional standards [104] (see Section 1.6.5). Finally, our findings show that radiologists report that they make significant efforts to provide appropriate imaging services (Article IV). That radiologists so frequently need to take action against inadequate referrals can be seen as a token of an ever more complicated and sophisticated service that requires an active and responsible practising radiologist. Hence, their position is central when discussing norms and measure to manage imaging utilization.

[84] As utility of services is largely associated with the appropriateness of the examinations, the term appropriate may appear in the discussion as an indication of utility.
[85] In addition, it may be morally wrong to place responsibility for use of imaging on the patients' shoulders [185].
[86] Recording cumulative doses in the patient's file might however have some effect. The requirement of recording radiation doses is reinforced in the new Radiation Protection Regulation [186].

5.2.1 Radiation protection legislation

An important norm regarding utilization of imaging is the requirement of justification of examinations in the radiation protection legislation, established by governments and radiation protection authorities. The expected benefit of this norm is to protect the population from unnecessary exposure to radiation. Alternative methods to CT and plain x-ray examinations should be considered, and MRI, ultrasound or a non-radiological examination (e.g. clinical) should be chosen whenever feasible. But there is also an obligation to consider the benefits to society, e.g. by choosing ultrasound before MRI due to lower costs. Certainly, the chosen alternative examination must be able to provide sufficient diagnostic information.

Despite these expected benefits and despite the fact that the justification norm is stated in the Norwegian legislation, this norm does not seem to have had a profound beneficial influence on practice. There are several empirical indications that it is not always followed, e.g. unnecessary examinations do occur according to the radiologists (Article III), assessment of the justification for plain x-rays seems not to be performed readily in radiological departments/institutes, and the use of CT has shown a remarkable increase with an accompanied increase in radiation doses (Article I). A reason for poor compliance to this norm is that it requires an *act*-utilitarian assessment:

> "In the assessment [of justification] account shall inter alia be taken of whether the benefits outweigh the potentially harmful effect due to the use of radiation. Account shall be taken of the benefit to the individual, the benefit to society and whether alternative techniques can be applied. The use of radiation shall be avoided in cases where the same result can be achieved by other means without material inconvenience, for example by using other methods or by obtaining results from previous examinations." [22, Section 13].

This statement illustrates one of the classic problems in act-utilitarianism. It "requires computational powers that we do not have, and cannot ever get" [99]. We easily see the "brain overload" if we try to consider all kinds of benefits, harm and risks, balance these against each other, with respect both to the individual and to society, and then again compare this with (a number of) alternative actions, not to mention the difficulties of interpreting phrases like 'the same result', 'material inconvenience' etc.

What makes the assessment in clinical decision-making for imaging additionally difficult (and an act-utilitarian approach challenging) has to do with time distances. First, there is often a long time span between the examination and the final outcome for the patient, and because the therapy is an extra intermediary step, it is harder to connect the diagnosis with the outcome [168]. Second, the radiation involved represents a small and remote risk, [87] which may appear trivial compared to the risk of not discovering serious disease by choosing a wait-and-see strategy or the like. This may contribute to a low awareness of radiation risk [187,188], and obscure a constraining effect of risk assessment on imaging utilization.

Still, our findings show that concern for radiation protection influences the radiologists; high radiation dose was the second most important reason for radiologists to act towards inadequate referrals. Radiologists probably conceive the core content of the legislation as an action-guiding rule, and practice accordingly in a simplified manner. When assessing a concrete referral, they may, for instance, think: Should we perform a CT examination in this case, or can ultrasound provide equally informative results? Nevertheless, the legislation needs support from norms and measures with content that can guide choices and action better in clinical practice.

5.2.2 Clinical guidelines

Clinical guidelines can reduce uncertainty and facilitate appropriate use of radiological examinations by avoiding overuse and underuse of services, and avert waste of resources [15,189]. Clinical guidelines are seen as the most important tools in utilization management [15]. They are practical applications of evidence-based radiology, which are rooted in the ethical imperative to avoid unnecessary harm, to benefit patients, and to act justly by eliminating waste [128]. Avoiding over-utilization can affect the radiologists' work positively and increase "efficiency by using the right test at the right time" [15]. The radiologist community has therefore made a great effort, and invested many resources, in establishing and up-dating clinical guidelines [113,190], which are now available in many countries.

Clinical guidelines can also have beneficial consequences beyond those that follow directly from the impact on acts. Patients may be reassured by being aware that such guidelines are accepted, so that their examination or treatment does not depend entirely on individual professional judgement. To professionals, acceptance of guidelines can improve the foresightedness of how their colleagues will act.

[87] Besides, the radiation risk is basically uncertain due to its stochastic nature and the impossibility of ascribing particular cases of cancer to radiation exposure.

However, it seems that the "transition" costs of getting clinical guidelines widely accepted have been underestimated, as warned by Hooker [86]. Even though guidelines may be accepted, implementation in clinical practice seems to be very challenging [191-193]. The "… effectiveness of guidelines in modifying clinical practice varies considerably" and well-developed and disseminated guidelines may still be ignored by practitioners [16]. A recent study reported a significantly low adherence; only 2.4% of the various specialities' clinicians made use of the ACR Appropriateness Criteria [194]. The authors suspected a general unawareness of the criteria's existence, which may seem surprising, since it is fifteen years since their inception. In Norway, we have evidence of low adherence to guidelines from a study that showed that only 1/4 of plain radiography of the lumbosacral spine conformed to Norwegian guidelines and roughly 1/3 conformed to the British guidelines [195]. Indirectly our findings support the suspicion that the referral guidelines are not readily used, as the radiologists report that they frequently act on inadequate referrals (Article III).

Certainly, for clinicians to find referral guidelines useful they have to be known and easily available, which is a task for the radiologists' community. This again presupposes that radiologists promote and make active use of the guidelines. In a survey by Tigges et al. only 30% of the radiologists reported that they used the appropriateness criteria, and rarely for guidance purposes [196]. They suggest that: "More effective ways of influencing the day-to-day practice of radiologists might include using outreach visits or local opinion leaders to educate radiologists" [196]. There are thus reasons to believe that the guidelines could have been promoted better both among radiologists and referring physicians, also in Norway. [88]

In the search for definitions of diagnostic futility, Hofmann points out that adherence to guidelines "would not address the question of excessive imaging" because guidelines may be interpreted differently among professionals [110]. However, guidelines in clinical practice are surely never meant to replace, only to support, medical decisions [197]. This means that the only reasonable approach to understanding clinical guidelines is in terms of non-compulsory rules as in act utilitarian. It must be allowed for the clinician and radiologist to act against the

[88] The Norwegian referral guidelines are a translated version of 'Making the Best use of a Department of Clinical Radiology: Guidelines for Doctors', (5th edition) developed and published by the Royal College of Radiologists in the UK. They are available at the website of the Norwegian Society of Radiology http://www.radiologforeningen.no/external/guidelines/INDEX.html, but I have not found any documentation of strategies to disperse and promoted them among referring physicians.

guidelines whenever the patient's condition requires them to do so. This is important to bear in mind when assessing more "mechanical" applications of guidelines.

Computer-based decision support systems

Systems like Physician Order Entry (POE), [89] computer programs with decision support, have been developed by radiologists with the aim of helping clinicians to select appropriate imaging procedures, and thereby to enhance quality and lower costs [69]. This is seen as a way of tackling the over-utilization problem that requires few resources from radiology departments [69]. The impact on ordering practice is partly promising [16,198,199]. Such systems seem to be able to resolve two closely linked problems identified in our study: missing clinical information and doubts about adequateness of referrals (Article IV).

A major problem with such an approach is that the "need to justify procedures creates the tendency to supply clinical details which will "guarantee" that a certain desired investigation be performed" [80]. It is a reported side effect of guidelines in general that "prescribers may begin to use documented referral criteria inappropriately so that they may be assured an examination they want will be performed" [200]. In this way, what we gain is *seemingly* more appropriate and useful examinations, i.e. a more hidden and hence more difficult problem, because the radiologists are deprived of a) the possibility to take action towards providing a more appropriate examination, and b) complete and correct information as the basis for the examination report.

In summary, clinical guidelines are essential as professional norms, hence readily used in the assessment of appropriateness and quality of referrals in empirical research. Guidelines could improve utility of imaging further if more efforts were made to adopt them in clinical practice in a proper manner. However, it is far from obvious that guidelines, with or without computer support, could render radiologists' assessment and consulting services superfluous.

[89] The POE software in the United States is based on appropriateness criteria from the American College of Radiology (analogous to the European guidelines), where the requested examination "is scored, real time, for its appropriateness (according to the specific clinical situation) using a nine-point scale" [69].

5.2.3 Communication and radiology consultants

Picano et al. are probably right when they state that "lack of communication and imperfect exchange of information are often at the basis of inappropriateness" [14]. Multidisciplinary collaboration and peer-to-peer consultation are important to promote both optimal patient care [15,194] and control of utilization [15]. Accordingly "radiologists should be available for consultation with other specialists before they order advanced imaging procedures" [15]. Referring physicians also seem to prefer consultation with the radiologist when they need information for making good referral decisions for their patients [194]. However, they rarely consult with the radiologist [35,201,202], except when requesting angiographic or interventional procedures [201,202], which entail greater risks and are more expensive.

The utility of an open line of communication with the clinician is evident to radiologists. In this way they obtain "invaluable clinical information that could provide a more accurate and clinically applicable interpretation of the study" [194]. Not surprisingly, our study showed that the most common strategy by radiologists when confronted with doubtfully useful referrals was to confer with the clinician (Article IV). At the same time, many radiologists reported being somewhat hindered by time pressure and difficulties in getting in touch with the clinician.

Clinician-radiologist consultations are time-consuming [203], and lack of time may be a main reason why the consulting role of radiologists is said to be ignored both by themselves and by the referrers [76]. New technology may lead to even less personal contact between the clinician and the radiologist. It is interesting that "many clinicians insisted that the traditional radiology rounds should be continued as before" when "integration of electronic patient record (EPR) with a radiology information system (RIS)" was introduced [204]. This might not necessarily reflect a conservative reluctance, but rather a perceived usefulness of professional personal meetings. One may wonder how efficient these measures to improve efficiency, by means of new technology, really are, and whether they entail "invisible" losses of quality and utility of services. The utility of radiologic consultation may not be fully replaced by other means, but the curtailment of the arenas for such communication may increase the need for radiologists' vetting of referrals.

5.2.4 Vetting of referrals

By following a norm to vet actively, to screen or to preauthorize referrals in radiology departments and institutes, we can abate inappropriate examinations, and improve utilization and utility. Such a norm would serve as a "critically important filter between the referring and the practicing physician" [14]. Preauthorization of request has been tested with promising results [112].

However, it does not seem as though the norm of critical assessment is followed. The justification process has been reported to be "sometimes weak, or non-existent, or at the very least lacks transparency" [205]. [90] It has been stated that the booking system in many places is a passive and merely administrative channel [14]. One reason may be insufficient grounds of accomplishing a proper vetting of the referrals. Insufficient clinical information and unclear questions in the referrals [91] are common phenomena in Norwegian radiology departments and institutes. 84% of the radiologists replied that this occurred to at least some extent in their own workplace (Article III). In this situation, they are left with three choices, all with possible negative impact on utility of services. First, they can make an effort to obtain the required information, which we found was a common and frequent strategy (Article IV). The radiologists reported that information was largely requested from the referring physician, from the patient and traced in the medical record. It has been argued that seeking further clarification is an ineffective use of staff time that should be avoided [200]. Second, they can refuse to carry out the examination and return the referral, which our respondents reported they rarely do. This can cause delay of imaging to the patient [200]. Third, they can let the examination be performed and analysed, and the result reported, despite lack of clinical information and uncertainties about clinical questions. In this case they are risking several adverse consequences:

> "performance of unjustified and unnecessary exposures; application of inappropriate radiographic technique or projections; [….] radiological reports that may not address the actual clinical suspicion; inaccurate reports; and waste of resources with concomitant financial implications" [200].

The scope of this latter practice is unknown, as we did not ask the radiologists how often they choose not to act or intervene when confronted with inadequate referrals.

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[90] Justification of examinations was one of the major issues pointed out at a European workshop on ethical issues in diagnostic radiology and insufficiency in practising justification gave rise to extended discussion and much concern [205].

[91] The referral form should include the following medical patient data: "possible diagnosis and working hypotheses, signs and complaints, medical history, physical examination, medication, and the reason for the request" [206].

Emphasized reasons for insufficient vetting of referrals are time constraints [14] and costs, i.e. considered not feasible in low-cost examinations [15]. In addition, the referral system may be a barrier when it "requires a specific test to be requested, instead of enabling the radiologist to recommend the most appropriate diagnostic test in the clinical situation" [207]. This has been reported to cause ineffective use of radiologists' expertise in Australia [207]. In Norway, referring physicians are not obligated to specify modality in the referral form, but they are expected to, and they most often do [208].

Additionally, there may be some cultural obstacles for vetting and booking control to be useful measures. According to descriptions from the United States, the radiologist is seen as a "service provider and consultant to other departments, and it is common practice to simply perform the procedure requested by the clinical team." [194]. Similar opinions may be present in our context. One finding suggests that Norwegian radiologists regard clinicians to be ultimately responsible for examination choices: the major factor in favour of performing an examination, despite the radiologist's doubt about its usefulness, was respect for the referring physician's professional judgment (Article IV). [92] If the referring physicians are not accustomed to having their referrals corrected or rejected, they may not tolerate this, and an attempt to do so could lead to unpleasant encounters [194,209]. Extensive vetting may also cause adverse reactions like adjustment of the clinical information (as explained regarding the guideline strategy), or they may turn to "another radiologist in order to gain approval for a request at the margins of appropriateness" [210].

On the other hand, active assessment of referrals has been reported to give favourable reactions from referring physicians [196]. From our study, we can assume that it is relatively common that radiologists correct the clinicians' request by changing investigation technique/modality, and also to refuse a small fraction of referrals. The latter is supported by another Norwegian study [201]. This indicates that Norwegian referring physicians accept that radiologists intervene regarding their referrals. When referring patients to radiological institutes, they can in fact pre-approve (by signature) that the radiologist may change the type of investigation. Demonstrating responsibility in examination choice may also enhance the clinician's trust in the radiologist.

[92] Another, perhaps more plausible interpretation of this finding, is trust in the assessment of a clinician they know normally makes wise decisions.

There are indications that Norwegian radiologists largely accept responsibility for assessment of referrals, and that this is a regular part of their practice. Almost all radiologists in our study reported to take some action in response to inadequate referrals daily or weekly (Article IV), which must include a prior referral assessment. Willingness to accept responsibility is clearly stated by the Norwegian Society of Radiology in a recent submission to a draft of the new Radiation Protection Regulation. Here, it is argued that the concept *prescription* or *requisition* (Norwegian: rekvisisjon) should be replaced by *referral* (Norwegian: henvisning) because this "better reflects that the indication for the examination and the examination method is to be assessed by the enterprise where it shall be performed" [211]. At the same time, it is asserted that it is impossible for radiologists to vet all referrals, and that common practice is that referrals for plain x-rays are only assessed by the radiographers or the office staff. It seems illogical that choice of modality in a referral should be decisive regarding whether a proper medical assessment by a radiologist is necessary, when choice of modality is one of the important things to assess. According to our survey, plain x-rays still constitute 60% of all examinations (2002 figures (Article I), which may be slightly lower today). Consequently, the majority of referrals are not an object of a proper medical assessment in the radiological institutions, i.e. assessment of clinical indications and appropriate choice of modality.

Moreover, some of the radiologists' reported actions, typically to gain information from the patient, reveal that vetting takes place when the patient is already present (Article IV). Arrival of the patient was also rated as the second most frequent factor contributing to an examination being carried out, despite doubts about its usefulness. It is reasonable that radiologists may find it difficult to handle inadequate referrals while the patient is waiting, and in the worst cases send a patient who is prepared for the examination home.

Does this mean that 'the patient has arrived' can count as a special condition that legitimates not following the norm of assessing the justification of the examination? One could argue that not to follow the norm would produce the greatest goods in this situation, by not confusing or disappointing the patient, and the time spared by just having the examination done. However, the utility account may turn out differently regarding the long-term consequences (as indicated above). Furthermore, the reason for breaking the rule is not very weighty, as it is the result of how the work is organized, which the radiologists should be able to influence. This is also true for practical vetting obstacles in general, like time constraints and the fact that the radiologists do not see the referral before the examinations are performed. [93]

When assessing possible measures to manage utilization, it is important to bear in mind that the radiologists' vetting sometimes takes place too late and does not include all referrals. Surely, the radiologists and their managers know that careful vetting in the long run could save them from time-consuming handling of unnecessary examinations. The question is whether they regard this as sufficient to justify increased vetting efforts. They may assess the short-term consequences as very demanding, or there may be other weighty values (e.g. economic) not supporting such a measure. There are (at least) two more variants of vetting strategies to consider.

First, the radiologists could delegate a more comprehensive vetting of referral to the radiographer. The radiographer is often the first and only health care professional interacting with the patient in the radiology department. They are in a good position to recognise cases of duplicate examinations, questionably indicated examination, and patients undergoing multiple similar examinations [3]. Their responsibility in such cases is to notify the radiologist [ibid]. The Norwegian Society of Radiology indicates that Norwegian radiographers are delegated some similar responsibilities [211], like checking the sufficiency of referral information and patients' recent imaging history. Radiographers can be delegated expanded responsibilities for referral vetting, as practised in the UK, but this requires that sufficient training is provided.

Second, referrals for radiology could be handled like other referrals for medical specialities. This implies leaving the choice of examination to the radiologist based on patient symptoms, anamnesis and clinical questions described in the referral. [94] This idea has been recognized and discussed by Norwegian radiologists for a long time [212,213]. The utility potential is apparent, because the alternative seems unnecessarily cumbersome and resource demanding: to endeavour to make the referring physicians aware of and adhere to guidelines, and then expect radiologists to assess and review the referring physician's choice of imaging and

[93] That radiologists have an ability to influence how the referral system is organized means that they have an obligation to prevent possible unnecessary examinations, even if they claim it is impossible to vet all referrals. It is not a matter of *cannot* that implies *no obligations,* because it is beyond the physical or physiological abilities of human beings, hence it cannot be defended from a professional ethical perspective.

[94] Neither physicians nor patients find it strange to leave equivalent decisions to other specialists, but willingly accept that e.g. surgeons decide if surgery is indicated and what kind of surgery to perform etc. Clinicians' and patients' knowledge about radiology is hardly significantly better than about surgery, still patients wish to influence imaging choices, and clinicians are expected to choose between modalities.

negotiate if they disagree. [95] This strategy would not render the need for vetting of referrals in the radiology department superfluous, but change its content. A major challenge could be that the suggested measure requires very thorough and extensive clinical information, though in such a situation clinicians would probably realize the utility of providing this. The reasons why it seems somehow radical to increase radiologists' discretionary power in this way can be practical, cultural and/or perhaps because of doubt about its utility.

5.2.5 Increasing the discretionary power of the radiologist

Above I have suggested that radiologists, in one way or another, should have more influence on whether, when and which examinations should be performed. In the following, I will elaborate further on the overall implications of such measures. Can we expect a change in the utility of services by giving radiologists more influence in the decision-making process? I consider changes likely regarding three aspects of utility: a) appropriateness and patient doses, b) the action guiding value of the examination, and c) societal utility and cost control.

Appropriateness and patient doses

Our findings show that the main reasons for radiologists to act towards inadequate referrals are patient safety considerations: high risk of serious complications or side effects, high radiation dose and low patient age (Article IV). Accordingly, we should expect radiologists to channel patients to non-ionizing modalities whenever feasible, typically MRI or ultrasound. Such approaches have been tried with promising results in Norwegian studies, i.e. a shift in imaging modalities towards MRI and ultrasound, partly due to a radiation protection policy in the radiological department, has reduced radiation doses to patients [214,215]. Patients would benefit from this risk reduction based on the radiologists' professional knowledge.

By increasing radiologists' influence in the decision-making process, in general we should expect more appropriate examinations, i.e. examinations medically useful and in accordance with the guidelines. This assumption is grounded on the high rating of over-investigation (i.e. because clinicians rely on investigations and patients take comfort in being investigated) as a cause of unnecessary investigations (Article III). Clinicians are exposed to patient pressure and reliant on gaining the patients' confidence [216], much more than the radiologists. Hence,

[95] A study in the USA showed that radiologists used the appropriateness criteria "most commonly for utilization reviews or to validate a particular choice of imaging with a clinician" [196].

it should be easier for a radiologist to emphasize medical appropriateness in the assessment of a requested examination, and to avoid over-utilization. However, they report being somewhat responsive to patients' wishes: one half of the radiologists responded that 'patient/next-of-kin wants the examination' would to some extent or more contribute to performing an examination of doubtful usefulness (Article IV). If the radiologists had more influence on examination decisions, they could be more exposed to patient pressure for examinations, a pressure that is generally hard to resist [217,218]. However, this scenario is implausible, because patients do not normally know the radiologist and the patient is rarely present when the radiologist assesses the referral. A more likely scenario is that pressure on the radiologist from the referring physician would be more persistent, on the patients' behalf.

Radiologists should be familiar with standing in the "cross fire" between stakeholders with diverging interests:

> "… a patient […] will want to be imaged with the best available tests and with multiple imaging modalities. […] A manager in the radiology department or hospital will be more concerned about the budget. The health care policy maker ideally takes a societal perspective and is concerned about making and keeping the health care system affordable and sustainable"[160].

Both the referring physicians and the hospital administrators are said to want more examinations, while third party payers and those concerned about radiation dose demand less [69]. In this setting it is claimed that radiologists are in the best position to handle different interests and pressures [82], presumably because their interests and incentives are considered more balanced. Radiologists' own interests, i.e. to preserve their income and to perform high quality services, may not unambiguously point in one direction regarding utilization and utility of services.

The action guiding value of examinations

According to Korsbrekke [219], the clinician may want the radiological diagnosis to be as conclusive as possible (i.e. a high specificity), contrary to the radiologist, for whom it may be most important to distinguish normal variation from early signs of pathology, and not to miss any pathology (i.e. a high sensitivity). Surely high sensitivity may have high action-guiding value, e.g. in cases of lung cancer, to exclude lymph node metastasis before surgery. But if the emphasis on high sensitivity leads radiologists to choose one or more investigation technologies that provide maximum and detailed information – surpassing what is useful for the clinician's further management of the patient – the radiologist's influence may compromise the action-guiding value of the examination, and thereby the utility of the services. Besides, from their perspective, it may be important to report all abnormalities in detail and to make recommendations regarding further diagnostic imaging procedures [78].

Radiologists may not be equally confronted with the questions of how to handle the information they provide as are clinicians, although they may be asked for advice regarding follow-up investigations. After all, clinicians are ultimately responsible for further management of the patient. If radiologists are somewhat unaware of the limitations of the clinical value of the information, they may regard incidental findings as primarily positive. This is challenging due to potential futility and the risk of harm [129]. For instance, small lung nodules identified on CT angiographies implies uncertain, but potentially malignant aetiology. According to Wann et al. [78] follow up of such findings often entails more CT scans, and sometimes bronchoscopy, lung biopsy and lung resection, i.e. invasive diagnostic procedures with high risks of morbidity and mortality. What further complicates patient management in such cases is that "the utility of CT in detecting lung cancer at a point early enough in its natural history to prolong life or relieve suffering remains unproven" [78]. The problem of uncertain utility of radiological findings is particularly relevant in the debate about adopting the many radiological screening tests that are becoming more available: mammography, aortic ultrasound, calcium scoring, lung cancer detection, carotid artery imaging and bone densitometry etc. A utilitarian analysis may not be very helpful in this debate, because of the difficulties in assessing and balancing the different values involved, values to the individuals and to society.

Societal utility and cost control

Increased influence of radiologists in imaging decisions may affect capacity of services and health care costs positively. This follows from the argumentation above regarding improved appropriateness, e.g. resources are saved if unnecessary examinations are curbed by letting the radiologist lead the patient directly to the most appropriate examination. Such cost saving effects could be somewhat reduced by two factors.

First, radiologists may tend to prefer the more advanced and costly MRI examinations due to diagnostic capability and radiation protection considerations. They appear to be far more concerned about utility in the shape of benefit and risks to the patient rather than societal concerns and costs. Contrary to patient safety aspects, we found that resource demands of an examination were rated low as a reason for preventing doubtfully useful examinations (Article IV). This indicates that a health care policy based on utilitarian cost-effectiveness analyses will not be convincing if it conflicts with professional judgement and morality. The reactions to the plan of acute phase CT examinations of head/brain for patients with concussion of the brain is illustrating: the professionals argued strongly against accepting increased radiation risk for the sake of societal cost savings [183]. [96]

Second, radiologists recommend additional or follow-up examinations (some reasons for this are given above). Such recommendations for further examinations, during the same visit or at a new patient visit, can be termed self referral [182] or "autoreferral" [66]. We do not have empirical research on this topic in Norway. Findings from the United States showed an overall fraction of repeat high-cost examinations of 31%, while radiologist recommendations accounted for only 8% [182]. There is a risk that increased discretionary power would add to radiologist-initiated follow-ups, particularly if combined with strong incentives to increase the productivity of imaging services.

In summary, the increased influence, and responsibility, of radiologists in examination decisions is expected to increase the medical utility of imaging by providing more appropriate examinations and removal of examinations that are clearly wrong or futile. However, the action guiding value of examinations may suffer and counter this gain slightly. We could also expect reduced collective effective dose to the population, and most likely an overall net benefit to society.

5.2.6 Health care policy and incentives

In this section, I will discuss two of the relevant ways health care policy making and management can influence utilization of imaging: directly by restricting availability/capacity and indirectly by giving economic incentives.

[96] This case is also interesting because it turns the view on the connection between futility and rationing upside down. According to Moratti, the questions of futility should not include rationing considerations [104], meaning that situations of rationing should not increase the likelihood of medical interventions being considered futile. However, in the case of these CT examinations, the rationing situation is the only reason for *not* considering the intervention as futile. Societal utility justifies otherwise futile examinations.

Restricting availability/capacity

In our different investigations of imaging utilization, availability emerges as a key explaining factor; regarding geographic variation (Article II), increased use over time (Article I), and indirectly unnecessary examinations (Article III). Availability of services can influence the use of imaging through supply of new technology [51], number of doctors available for providing services [45], travel distance to radiology facility sites [220], and whether there is open or restricted access for specialist practitioners [221]. These aspects of availability are sensitive to health care policy, and constraining capacity would be a powerful measure to manage the utilization of imaging.

In current Norwegian policy, the government does not control capacity of radiology services in detail. However, recently the South-Eastern Regional Health Authority lowered the upper limit for the utilization of MRI examinations (i.e. the number of examinations coved by public funding) as regulated in their agreement with private radiological institutes. [97] This was in response to growth in investigation volume. The results were long waiting times (up to two months), and debates in the newspapers, news broadcasts and question time in the Storting (the Norwegian Parliament).[98] It was argued that the restrictions jeopardized peoples' health and were unjust, because patients who paid themselves were offered immediate appointments by the radiological institutes. Reducing access to imaging services can be controversial and require a large amount of political courage, and the example illustrates that the authorities cannot assume support from the professionals or their institutions. Hence, other measures to restrict access may not be easily approved in the Norwegian context. Among the possibilities we find per capita contracting, where the radiology unit is paid a predetermined fixed fee to provide services for a certain population in a certain time period, regardless of how many examinations they perform. Another alternative is to let consulting firms provide guidelines and give preapprovals according to these [15]. The latter is not recommended "because it increases bureaucracy and complicates the image-obtaining process without translating into a higher quality of care" [15].

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[97] Private radiological institutes must have an agreement with one of the four Regional Health Authorities to receive public reimbursements for services.

[98] E.g. Aftenposten 13.06.08 http://aftenposten.no/nyheter/oslo/article2481881.ece?service=print; NRK Puls 19.01.09 http://www1.nrk.no/nett-tv/indeks/156541; NRK Telemark 26.08.09 http://nrk.no/nyheter/distrikt/ostafjells/telemark/1.6746927; The parliament 28.11.08 http://stortinget.no/nn/Saker-og-publikasjoner/Publikasjoner/Referater/Stortinget/2008-2009/081126/ordinarsporretime/14/

Nevertheless, in the long-term, awareness of limited capacity could lead to more careful considerations of the utility of an examination in individual cases, both by the clinician and the radiologist. It is also argued that constraints on capacity are "more respectful of physicians' autonomy and judgment than intrusive attempts to micromanage clinical decisions" [20]. However, Norwegian policy has largely made use of more indirect measures.

Economic incentives

Utilitarian influence in health care policy is evident, e.g. visible in slogans like "more health for the money". Productivity has become a significant norm expected to influence the utilization of health care services – including diagnostic imaging. Economic incentives are present both in ambulant and in-house radiology services. Ambulant services are financed by reimbursements and in-house services partly by activity-based financing (ABF). It is probably recognizable in the Norwegian context that: radiology departments are exposed to pressure to examine both inpatients and outpatients as quickly as possible, because delay for inpatients can prolong expensive hospital stays, while reimbursements for outpatients can be directly profitable for the institution [69]. Increased investigation volume (Article I) should therefore not be surprising. The impact of personal economic incentives was pointed out in a European study: it showed that counties with the highest use of imaging also had a much higher proportion of radiologists and other doctors who were paid per examination rather than by receiving a fixed salary [45]. [99]

It has also been claimed that economic considerations contribute to *overuse* of services, such as when physicians and hospitals are paid more when they do more [20], and when repeat examinations are performed in order to "minimize the overall cost of the patient's episode of care" [182]. Our findings suggest only a modest contribution to such a practice by the radiologists. We asked them if 'demand for efficiency at work' contributed to doubtfully useful examinations being carried out, and the majority (64%) replied that it did only to a small or very small extent (Article IV). This finding does not exclude that productivity pressure exists; only that this does not seem to make radiologists perform examinations of doubtful utility. There are other indications that radiologists feel an increasing economic

[99] The 10 European countries were divided into 3 groups according to x-ray (i.e. plain x-ray and CT) examination frequency. Group 1, Germany, Belgium and Luxembourg, perform 900-1200 examinations per 1000 population; Group 2, France, Switzerland and Norway perform 700-800; and Group 3, Sweden, Denmark, the Netherlands and the United Kingdom perform 450-600 [45].

influence and productivity pressure, illustrated by the following comment in the journal of the Norwegian Society of Radiology:

> “Facing times with expended possibilities, more patients and a mountain of routine examinations, we are surrounded by economic rhetoric. The management talk about profitability and volume. We receive reports about increased production, nothing about us helping more people. The industrial concepts drain our work for meaning and suck the essence out of our mission as physicians.” [222] (My translation).

There is a risk that economic rationality discourages responsible practice. Professionals are also exposed to conflicting incentives, as we expect them to act in the best interest of patients and to manage public resources in a fair and responsible manner, while practical policy and financial incentives push in the opposite direction. Moreover, an economic environment creates little room for professional reflections and actions. Radiologists do not find time to vet all referrals, which could have saved them from performing and reporting on futile examinations, i.e. production pressure can be a self-strengthening process.

Some of the expected benefits of increasing radiologists’ influence on utilization of imaging can be obstructed or reduced by productivity, time pressure and workload pressure. Golding and Shrimpton [79] give an example of how such pressure can increase patient doses. In order to save time, standard "catch all" protocols are replacing supervision by the radiologist and termination of the CT examination when sufficient information is delivered [79].

In addition, there is a risk that strong economic incentives to increase investigation rates may challenge the radiologists’ critical assessment of appropriateness and utility of examinations, particularly in a competing environment. Radiologists may not profit from proper vetting of referrals, because the referring physician may then turn to a less restrictive radiologist. Such effects of competition may contribute to the higher investigation rates in urban areas. We found that the coexistence of public and private institutions was a possible source of geographical variation (Article II). A remedy for managing utilization in this respect would be a more distinct division of tasks between the public and private sectors.

The concrete measure from the Storting to manage utilization of radiology services has mainly been to restrain economic incentives. During the last decade, the reimbursement rates and the activity-based financing portions of the payment have been reduced. [100] However, it seems as though the decrease in reimbursement rates has been compensated for by increased activity and extensive examinations of each patient. In private radiology, we find the strongest increase in investigation volume, use of more expensive examinations, and use of more modalities for each patient (figures from 2002-2006), while the corresponding changes for public radiology have been modest [151]. This suggests that the private sector may be more sensitive to economic incentives [221]. In general, current policy has probably been useful in the sense of constraining cost growth, while there are no indications of positive effects on appropriateness and medical utility of services. It may actually have had the opposite effect by increasing competition and productivity pressure.

In the literature, new models have been suggested that pay "physicians more for providing clearly appropriate procedures and substantially less for procedures of limited value" [14]. Of course, it is challenging to design a system that includes qualitative incentives, because quality is much more difficult to measure. However, it should be possible somehow to reward proper vetting of referrals or to include clinical indications in the reimbursement system. Professionals would probably approve an implementation of qualitative incentives, as this is compatible with how they think about and assess utility: emphasizing the medical usefulness to the individual patient. Radiologists' response to inadequate referrals is illustrating: when they choose the most time-consuming actions (as argued in Article IV), the likely reason is quality considerations. This indicates that *professional integrity* [101] is an important counter force to productivity incentives. Integrity and responsibility are sensitive to social processes; a strong group affiliation will therefore increase the likelihood that an individual can resist profit-motivated pressures from his employing institution [223].

We have not investigated radiologist's integrity, but our studies indicate that important factors influencing the utility of radiological services are influenced by radiologists' integrity. This means that professional integrity should be stimulated to increase utility of imaging. A crucial element in this approach would be arenas for deliberation on common understanding of professional standards and responsibilities. As mentioned above, traditional arenas for

[100] In 2005, reimbursement rates were halved and corresponding receipts transferred to the regional health authorities to promote their responsibility and opportunity for planning and prioritizing the supply of services in their own region [151].
[101] Integrity is one of the central virtues of health professionals, important in preventing professionals from actions that would compromise their professional and moral values [100].

communication and discussion are disappearing, [102] and need to be protected and/or replaced. In this context it is promising that radiologists seem to be increasingly aware of the need for them to increase their commitment and responsibility for appropriateness of services [30,32,60,76-80].

[102] Most markedly in teleradiology, where radiology services are "outsourced", making it possible for a radiologist to practise in total physical isolation. A discussion of the consequences of such a practice on the utility of services is highly needed, but beyond the scope of this thesis.

6 SUMMARY AND CONCLUSIONS

This dissertation provides empirical knowledge about different aspects of the utilization of diagnostic imaging and some related considerations of utility, which may be valuable for management of the services.

The survey of examination frequency revealed a significant increase in utilization from 1993 to 2002, largely due to increased frequency of MRI and CT examinations. These newer technologies tend to supplement rather than replace conventional technologies. The accompanying increase in the collective effective dose of 40% was considered relatively high. A plausible explanation is high accessibility of CT examinations in Norway.

Utilization varied the most geographically for MRI and CT examinations, and again we found indications of supplementary examinations. The study of geographical variation in examination rates suggests that accessibility is important for utilization of imaging, along with coexistence of public and private institutions and socioeconomic factors.

The survey of radiologists' perceptions further investigated factors influencing utilization of imaging. The findings points towards supply and demand mechanisms, with high ranking of factors related to expanded possibilities (technological and medical), availability of services and peoples' and referring clinicians' demands for assurance. Over-investigation to reassure patients and clinicians was regarded as a major cause of unnecessary radiological investigations. Another frequent cause of unnecessary investigations was insufficient referral information. These perceptions did not differ much between subgroups, except that institute radiologists reported lower occurrence of causes of unnecessary examination than did hospital radiologists.

The radiologists reported that they frequently take action in response to inappropriate referrals, mainly by searching for complementing information: by contacting the referring physician or by checking the medical records. Their actions seem to be primarily motivated by patient safety considerations: risk of complications or side effects, radiation dose, and low patient age. Their actions were somewhat hindered by respect for the referring physicians' judgment and patients' wishes, besides some practical obstacles: the patient had arrived, difficulties in contacting the referring physician, and time pressure. In choice of action there were some differences between registrars and radiology specialists, and between hospital radiologists and institute radiologists, while few differences between subgroup were found regarding factors affecting their decisions to prevent or not prevent an examination of doubtful usefulness.

The discussion of the usefulness of increased utilization of diagnostic imaging in the light of the empirical findings (our findings supported by others) indicates benefits in the shape of improved health outcome, reduced pain and lower costs, but also lack of such benefits and possible harm. All in all, utilization in Norway (and comparable countries) may have reached (or is approaching) a level where further increase will provide limited overall utility. Frequent over-utilization (with the risk of harm and increased costs) may easily outweigh the beneficial value of clearly useful increased use. The opportunity costs of imaging may also be relatively high, which points towards a potential for more useful allocation of scarce health care resources.

The norms and measures to manage utilization of imaging initiated by radiation protection and health care authorities seem to have a modest influence on utility of services. The radiation protection legislation is too complicated to guide practice. The reductions in reimbursement rates have decreased public costs, though these have been accompanied by an increase in investigation volume that may not add to medical utility. Approaches initiated by the professionals seem to be better at meeting the goal of increasing utility by avoiding or limiting examinations not considered to be useful. Clinical guidelines are important as norms of appropriateness, which so far have not been used to their full potential. I have emphasized that measures can and should be made in radiological departments and institutes to improve the utility of services. Radiologists should expand their role in the decision-making process, where critical assessment of referrals is a core element. Health care policy should be compatible with professionals’ norms and values and support their measures to manage utilization and improve utility of services, e.g. by giving incentives for quality of services.

Hopefully, this dissertation can increase awareness of problems and possibilities regarding utilization and utility of diagnostic imaging, both by professionals and policy makers. The findings may also draw attention to an almost terra incognita for the bioethicists to explore. In this way, the studies may have a normative value, by drawing attention to a problem area in medical practice.

7 FURTHER RESEARCH

In the present study, several issues that need further research are pointed out:

1. There is a need for continual surveying of utilization of diagnostic imaging, as the services are highly sensitive to the continuous development of new technology and changes in health care policy. Particularly, the incremental utilization of high-dose and high-cost procedures calls for attention.

2. Regarding geographical variation in the use of radiological services, further research should be based on patients' place of residence, and focus on the impact of accessibility. In addition, variation between small entities, like urban districts in the large cities, is so far unexplored.

3. Radiologists' perceptions of factors influencing the utilization of services, and their role in managing utilization and promoting appropriate investigations, is almost absent in the research literature. Hence, our findings need to be validated and completed by in-depth studies of radiologists' reasoning, and comparative studies in other contexts and countries.

4. Rigorous studies of utility are needed to evaluate whether increased utilization of imaging procedures facilitates the clinical decision-making process, whether patient outcomes are beneficial, and whether the societal costs are justifiable.

5. There are a number of unanswered questions regarding what measures would be most useful for improving the utilization and utility of imaging services. This calls for applied research e.g. on implementation of clinical guidelines, communication and collaboration in the decision-making process, efficiency of vetting procedures, and outcome of health care policy incentives.

6. Finally, while working on this project, I have noticed that the subject matter has received very little attention in the bioethical literature. One suggestion is to study imaging utilization within the framework of professional ethics, focusing on responsibility.

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II

BMC Health Services Research

Research article

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Geographical variation in radiological services: a nationwide survey

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Abstract

Background: Geographical variation in health care services challenges the basic principle of fair allocation of health care resources. This study aimed to investigate geographical variation in the use of X-ray, CT, MRI and Ultrasound examinations in Norway, the contribution from public and private institutions, and the impact of accessibility and socioeconomic factors on variation in examination rates.

Methods: A nationwide survey of activity in all radiological institutions for the year 2002 was used to compare the rates per thousand of examinations in the counties. The data format was files/printouts where the examinations were recorded according to a code system.

Results: Overall rates per thousand of radiological examinations varied by a factor of 2.4. The use of MRI varied from 170 to 2, and CT from 216 to 56 examinations per 1000 inhabitants. Single MRI examinations (knee, cervical spine and head/brain) ranged high in variation, as did certain other spine examinations. For examination of specific organs, the counties' use of one modality was positively correlated with the use of other modalities. Private institutions accounted for 28% of all examinations, and tended towards performing a higher proportion of single examinations with high variability. Indicators of accessibility correlated positively to variation in examination rates, partly due to the figures from the county of Oslo. Correlations between examination rates and socioeconomic factors were also highly influenced by the figures from this county.

Conclusion: The counties use of radiological services varied substantially, especially CT and MRI examinations. A likely cause of the variation is differences in accessibility. The coexistence of public and private institutions may be a source of variability, along with socioeconomic factors. The findings represent a challenge to the objective of equality in access to health care services, and indicate a potential for better allocation of overall health care resources.

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Background

Geographical variation in use of radiology has been documented in the United States [1-3], in Europe [4], and in the Nordic countries, where a factor of 1.8 in variation between the countries was reported [5]. When areas differ with respect to available economic resources, health care policies, referral systems, and reimbursement policies, then geographical variation can be expected. In Norway the health care system is predominantly public, and the National Insurance Scheme covers the vast majority of radiology services (including private radiology services), that is when patients obtain a referral from their physician (GP or specialist).

In an earlier study differences in use rates of radiology were observed between urban and rural areas in Norway, but the differences were not quantified [6]. To determine the presence and magnitude of variability of radiology is important with respect to the question of equal access to health care, which is a declared objective in Norwegian health policy (as in most other countries), and stated in The Patients' Rights Act [7]. Moreover, such data is valuable with respect to the question of allocation of overall health care resources, especially as radiology is a costly discipline, and expenditure on radiology is steadily increasing [8]. Although the question of the correct or reasonable level of utilization cannot be answered through small area variation analysis, a significant variation in otherwise homogeneous areas may indicate that use of radiological services, at least in some areas, is not optimal [2,5]; that is, that underuse or overuse occurs.

The aim of this study was to determine the use rates of radiology in Norwegian counties. Variation in overall and modality specific examination rates, i.e. X-ray (XR), Computed Tomography (CT), Magnetic Resonance Imaging (MRI) and Ultrasound (US), was analysed, as well as variability in clustered and single examinations. (In this study, XR includes conventional radiography, fluoroscopy, mammography, angiography and interventional procedures). In addition, the following hypotheses were investigated: a) counties with low use of one modality for examination of specific organs (locations) have correspondingly high use of other modalities, b) private institutions contribute to geographical variation, and geographical variation in examination rates is influenced by c) different aspects of accessibility and d) socioeconomic factors.

Methods

The Norwegian Radiation Protection Authority (NRPA) has conducted a nationwide survey to determine the frequency of radiological examinations during the year 2002. All medical radio-diagnostic procedures are included except dental examinations, nuclear medicine, bone densitometry and radiology in chiropractic settings and primary health care services. Activity data were received from all addressed entities (referred to as institutions in the following); 71 public and 9 private hospitals, 25 mammography screening laboratories and 25 private radiology enterprises. According to NRPA's registers these include all relevant institutions in 2002, hence the results are based on a complete count of the included examinations (not a sample survey).

The requested data format was files or printout from the Radiology Information Systems (RIS), where examinations are recorded according to the Norwegian Radiological Codes system (NORAKO) [9]. This system provides detailed information on the organ/organ system/anatomical region examined (location code), the modality used (modality code), the type of procedure to characterise/specify the examination (procedure code). Codes for right, left, or bilateral examination (side code) and codes for additional information (such as anaesthesia) are also included.

Data preparation

Of the 130 institutions, 13 did not report in the requested format. For 5 of these, the examinations were coded manually on the basis of received descriptive texts. For 8 (small) institutions that reported on examination group level (e.g. number of skeleton X-rays), average distributions for similar institutions were used to estimate the distribution of localization codes within each group.

The main adjustments carried out concern estimation of number of examinations from the number of codes. Since the codes are primarily used for reimbursement purposes, activities reflecting resources utilized in the examinations need to be specified. Consequently, one examination can generate more than one code. In general, codes were deleted when they did not represent an examination; either as stated explicitly by the institution (e.g. reinterpretation of radiographs) or by the user manual prepared by the Norwegian College of Radiology [9]. Procedure codes for additional series were deleted, except for six institutions where coding had clearly not been carried out in accordance with the manual. This adjustment has reduced the number of CT and angiography codes by 7.7% and 8.7% respectively, while 40% of the MRI codes were deleted. Moreover, in CT examinations 7.8% of the intravenous contrast (IV) codes were deleted to eliminate double coding (of examinations both with and without IV). This adjustment was estimated based on a previous survey of CT examination techniques [10]. In X-ray examinations (other than angiography) the number of codes was assumed to be equal to the actual number of examinations, due to a low probability of any kind of double coding. A more detailed description of the method is to be found in an extended report [11].

County was the entity used in the geographical variation analyses, based on the assumption that institutions mainly serve inhabitants in their own county. For mammography screening this was not the case; three screening laboratories provided services in two counties each. Consequently, these data were distributed according to the number of inhabitants in the respective counties. Moreover, for two large hospitals situated in Oslo (the Norwegian Radium Hospital Comprehensive Cancer Centre and Rikshospitalet University Hospital) the majority of the patients reside outside Oslo (close to 90%). Detailed information on patients' residential county and the corresponding number of examinations per modality was provided, and formed the basis for distributing these data.

Indicators of accessibility and socioeconomic status

The reported data on number of examinations are not linked to individual patients, hence correlations between examination rates and variables of accessibility and socioeconomic factors are provided on an aggregated level. Information on settlement characteristics (population density, percentage of urban settlements) and number of radiographers employed in the counties were obtained from Statistics Norway [12], while number of working radiologist in each county was obtained from The Norwegian Medical Association (on personal request). In addition the proportion of the counties population living in municipalities with general radiological services was calculated. This calculation was based on number of inhabitants in each municipality (the 19 counties are divided in to 434 smaller municipalities) and information of location of general radiological services (delimited by excluding mammography screening facilities and specialised rehabilitation and heart disease hospitals). This measure was applied to assess the impact of proximity, i.e. whether a high percentage of a county's population living in a municipality where a radiological provider exists could explain high examination rates. Socioeconomic information (average gross income for persons 17 years of age and over, and number of persons with tertiary or postgraduate level of education per 1000 inhabitants) was also obtained from Statistics Norway. The linked table displays figures of settlement characteristic, radiological resources and socioeconomic factors in the counties (see Additional file 1).

Statistics

Geographical variation is presented as rates (number of examination per 1000 inhabitants) in each county, high/low ratio for rates (an easily comprehensible measure), and the more accurate variation measure coefficient of variation (COV, which is defined as standard deviation relative to mean rate value). Pearson's r describes correlations. Statistical significance analyses is performed even though the results are based on complete count, seeing the year 2002 data as a sample of the true values that varies randomly across years.

Results

The overall reported rate per thousand of radiological examinations in Norwegian counties in 2002 varies by a factor of 2.4. The rate was highest in Oslo (the capital and the most densely populated county) and lowest in Finnmark (the most distant and sparsely populated county): 1487 and 613 examinations per 1000 inhabitants respectively. The linked map displays the location of the counties (see Additional file 2).

Geographical variation in the use of different modalities is shown in Table 1, in terms of examination rates. For every modality the rates were highest in the county of Oslo. The national mean rate in use of overall Computed Tomography (CT) was 104 examinations per 1000 inhabitants; the rate ranged from 216 in Oslo to 56 in Oppland (a mainly rural county in the eastern part of the country). This difference represents nearly a fourfold variation. The variation in use of Magnetic Resonance Imaging (MRI) was even greater. The national average use rate of MRI imaging was 61 examinations per 1000 inhabitants; the use rate ranged from 170 in Oslo to 2 in Finnmark. The variation in use of X-ray (XR) and Ultrasound (US) was less: The ratios of highest (Oslo) and lowest rates (Finnmark and Nord-Trøndelag) were 2.0 and 2.9 respectively. The coefficients of variation (COV) were 69% for MRI, 36% for CT, 27% for US and 2% for XR, i.e. the highest variation was found for the most recent and advanced technologies.

When examinations were clustered according to the region of the body (irrespective of the modality used), the highest variability was seen for spine examinations (COV: 39%, high/low ratio: 4.3). The least variation was found for 'chest' examinations (COV: 18%, high/low ratio 1.9). Medium variation was found for 'pelvis, urinary tract and genitalia', 'head', 'mammae', 'abdominal and gastrointestinal' 'extremities' (COV between 34% and 24%, high/low ratio between 3.9 and 2.2).

Geographical variation for single examinations is shown in Table 2, the 30 most frequent (of a total of 370) are included. Altogether these include 80% of all examinations reported. The three MRI examinations that were included (knee, cervical spine and head/brain) all ranged high in variation (COV: 103%, 79% and 47%). It can also be noticed that different kinds of spine examinations ranged high. XR thorax was the one that varied the least (COV: 16%). However, the rate of this examination was twice as high in the county of Telemark as in Oppland

Table 1: Number of examinations per 1000 inhabitants[1] according to modality and county in 2002, with high/low ratio and coefficient of variation (COV)[2]

County	XR	CT	MRI	US	Total
Oslo	921	216	170	180	1 487
Telemark	823	97	80	135	1 134
Vest-Agder	754	114	98	101	1 067
Troms	778	108	65	113	1 064
Østfold	691	122	84	139	1 036
Sør-Trøndelag	671	121	57	98	947
Buskerud	656	80	58	131	925
Vestfold	612	86	72	111	882
Nordland	576	106	60	94	836
Rogaland	589	89	34	95	807
Hordaland	573	95	25	88	781
Hedmark	565	83	12	102	761
Møre og Romsdal	544	72	29	103	749
Akershus	522	77	40	69	707
Nord-Trøndelag	533	78	33	62	706
Sogn og Fjordane	505	72	37	86	700
Aust-Agder	484	61	34	71	649
Oppland	484	56	26	82	648
Finnmark	459	72	2	80	613
High/low ratio	2.0	3.9	83.7	2.9	2.4
COV	20	36	69	27	24

[1] Total population in Norway 2002: 4 552 252
[2] COV is standard deviation relative to mean rate value within counties

(160 vs. 82 examinations per 1000 inhabitants respectively), two counties with similar demographic characteristics.

Correlations between different modalities

One could expect a tendency that a low use rate of one modality in examinations of specific organs (locations) corresponded with a high use rate of alternative modalities. However, the results showed a relatively high positive correlation between the uses of different modalities for specific organs of examination, as shown in Table 3. This was most pronounced for CT and MRI examinations of head/brain, CT and MRI of pelvis, XR and CT of thorax, XR and MRI as well as CT and MRI of cervical spine and finally XR and MRI of knee (all Pearson's $r > 0.63$ and significant at a 0.01 level, 2-tailed). Several other correlations are significant at a 0.05 level. Of the 24 correlations 23 was positive, the binomial distribution probability of this is lower than 0.000. The correlation for head/brain examinations is illustrated in Figure 1.

Contribution from private and public institutions

Figure 2 illustrates how public and private institutions contributed to examination rates per thousand. The private institutions mainly contribute to examination rates in counties in the central south eastern part of Norway, especially in Oslo. As examinations performed in private institutions accounted for only 28% of all examinations the geographical variations was mainly caused by public institutions. However, in single examinations the contribution from private institutions differed substantially and was generally higher in examinations with high variability. Private institutions performed e.g. 78% of MRI knee, 57% of CT lumbar spine and 55% of MRI cervical spine examinations. The correlation between the variations (COV) of the 30 most frequent single examinations (the same examinations as displayed in table 2) and the proportion of these examinations performed by private institutions, Pearson's r was 0.72 (significant at a 0.01 level, 2-tailed).

The impact of accessibility

The correlation (Pearson's r) between examination rates per thousand and the proportion of the counties population living in municipalities with general radiological services was 0.88 (illustrated in figure 3), i.e. accessibility (indicating proximity to radiological services) statistically explains 78% of the variance of examination rates. The population density's (population per km^2) correlation to examination rates was 0.69 and similarly the proportion of urbane settlement 0.63. The correlations between examination rates and number of radiologist and radiographers (measures of accessibility in the shape of available radiological resources) were 0.71 and 0.66 respectively. All correlations were significant at a 0.01 level (2-tailed). However, as settlement characteristics and radiological

Table 2: Geographical variation in number of single examinations[1] per 1000 inhabitants, in the counties with highest and lowest values, high/low ratio and COV within counties

	Highest	Lowest	High/low ratio	COV (%)
MRI Knee	37	0.1	304.1	103
US Pelvis	17	0.2	86.7	79
MRI Cervical spine	21	0.2	139.0	79
XR Lumbar spine	29	2.0	14.4	78
US Upper urinary tract	22	2.8	8.0	57
CT Lumbar spine	34	3.5	9.6	51
US Mammae	21	2.5	8.3	50
MRI Head/brain	26	0.8	32.4	47
CT Pelvis	22	4.4	5.0	45
XR Lumbar spine with sacrum	39	7.0	5.5	44
XR Cervical spine	43	9.6	4.5	40
XR Pelvis	54	13.9	3.9	37
CT Abdomen	24	7.5	3.2	34
CT Thorax	20	6.1	3.3	33
XR Thorax, front	71	14.3	4.9	32
XR Shoulder	46	13.9	3.3	31
XR Thoracic spine	14	4.9	2.9	31
US Abdomen	39	9.7	4.0	30
XR Urinary tract/ urography	18	7.2	2.5	27
XR Mammography	105	33.2	3.2	27
XR Knee	57	21.5	2.7	26
CT Head/brain	52	19.7	2.7	25
XR Foot	38	16.2	2.3	25
XR Ankle	36	16.6	2.2	23
XR Hip	64	28.7	2.2	23
XR Lower leg	13	5.3	2.4	23
XR Hand/fingers	41	13.7	3.0	22
XR Elbow	13	5.7	2.3	22
XR Wrist	33	12.2	2.7	22
XR Thorax, two projections	160	82.2	1.9	16

[1] The 30 most frequent examinations are included

resources in Oslo seem to be substantially different from the other counties, correlation was also performed without Oslo. This diminishes all the correlations; only slightly for the proportion of the counties population living in municipalities with general radiological services (to 0.82, still significant at a 0.01 level), more markedly for urban settlement (0.41), even more for number of radiologists and radiographers (to 0.23 and 0.15), while the cor-

Table 3: Correlations (Pearson's r) between examination rates according to modality[1] within counties

Examination	XR and CT	XR and MRI	XR and US	CT and MRI	CT and US	MRI and US
Head/brain	-	-	-	0.78**	-	-
Cervical spine	0.35	0.73**	-	0.68**	-	-
Lumbar spine	-0.06	0.38	-	0.56*	-	-
Thorax	0.75**	-	0.11	-	0.15	-
Abdomen	0.51*	0.35	0.28	0.31	0.21	0.22
Urinary tract	-	-	0.51*	-	-	-
Pelvis	0.63**	0.55*	0.39	0.75**	0.52*	0.62**
Knee	-	0.70**	-	-	-	-

[1] Correlations are only displayed if both modalities are frequently used for the examination in question, i.e. more than 1 per 1000 inhabitants nationally
* $p < .05$, ** $p < .01$

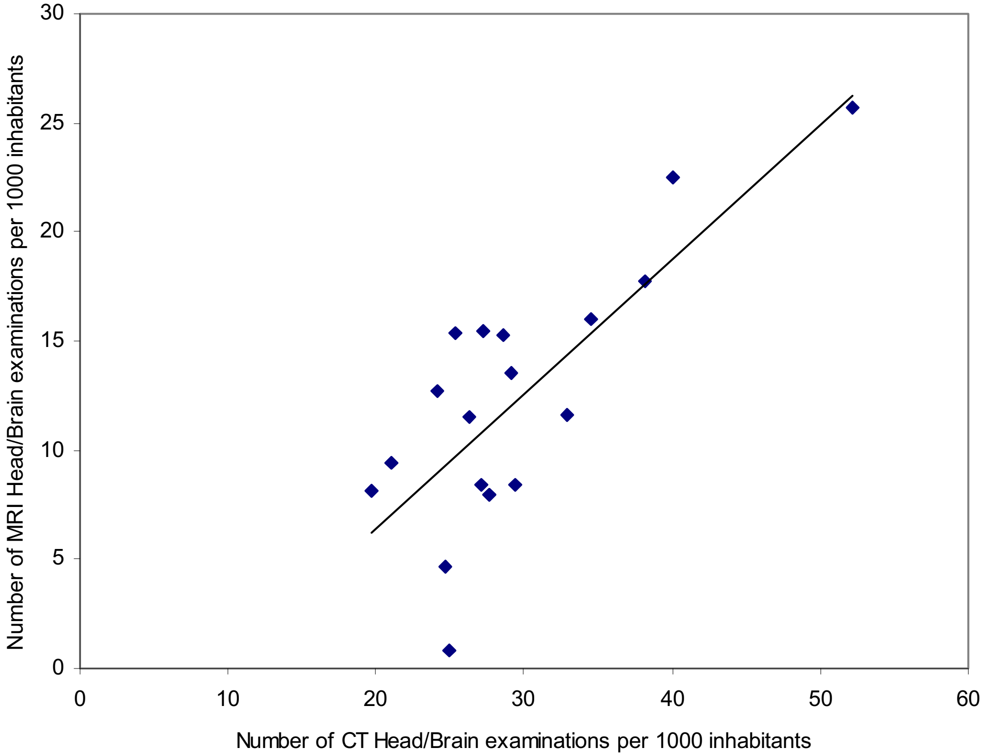

Figure 1
Correlation between rates per thousand of CT and MRI Head/Brain examinations in Norwegian counties. Regression line is displayed.

relation for population density vanished (0.09). None of the 4 last variables correlations were statistically significant.

The impact of socioeconomic factors

Two socioeconomic variables were used in this study; the number of persons with tertiary or postgraduate level of education per thousand inhabitants and the average gross income. The educational level variable correlated positively to overall examination rates (Pearson's r = 0.59, p = .008), while the income correlation was not significant (Pearson's r = 0.45, p = .056). Again the influence of Oslo was striking: the correlations vanished when the county of Oslo was not included in the analyses (r = 0.05 and 0.008 respectively). In Oslo the gross income level and the number of persons with highest level of education was a factor 1.3 and 1.8 above mean values in the counties respectively.

Discussion

The geographical variation in use of radiology was significant, not least as Norway traditionally is considered to be an egalitarian society where great emphasis has been placed on equal access to health care services. Most studies of variation rates in radiology are limited to single examinations and/or limited to particular populations. Hence, it is difficult to assess the level of overall variation found in our study compared to other studies. However, our

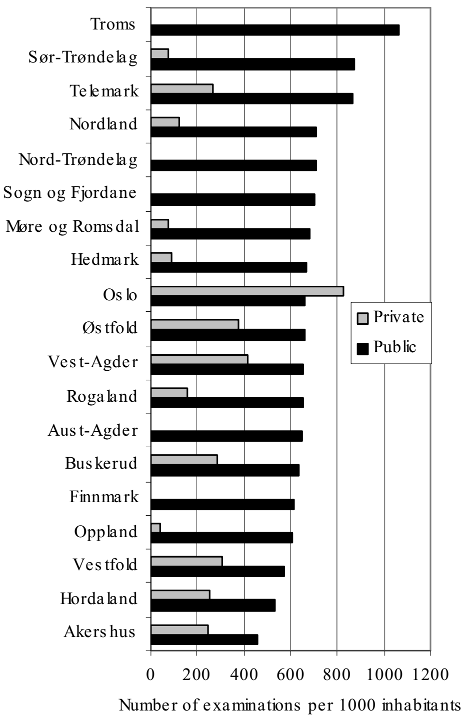

Figure 2
Rates per thousand of all radiological examinations in Norwegian counties, performed in public and private institutions.

study is very much in line with results from studies of geographical variations with regard to particular modalities, such as CT and MRI [13].

Validity of the data
The chosen data format was considered appropriate, as almost all institutions used the same coding system (NORAKO), it was convenient for the institutions and secured both a complete response rate and a uniform format. Nevertheless, some methodological considerations need to be discussed. The main challenge concerns estimation of the number of examinations from the number of codes. After deletion of codes that only described details about how the examinations were performed, we regard the number of examinations as almost correct. The exception is angiography/interventional procedures (and to a small extent ultrasound examinations) where data were not adjusted for the use of several location codes within a single examination. This means that the total rates per thousand was overestimated. However, the possible effect on geographical variation is small since angiography/interventional procedures accounted for only 2% of all XR examinations. If the estimation deviates in any other way from the real number of examinations, this would have a minor influence on geographical variation, as all institutions were treated in an equal manner. It could be argued that this presupposes that all institutions used the coding system in exactly the same way. When coding practice was scrutinised some differences between the institutions were discovered, possibly due to somewhat ambiguous guidelines. However, there were no systematic differences between the counties.

Migration as a cause of geographical variation
One obvious challenge to validity is patient migration (from one county to another). For two large hospitals (both situated in Oslo) examinations were distributed according to patients' home county. Nevertheless, patient migration may take place in other institutions and be a challenge to validity. Factors reflecting different aspects of accessibility could influence migration, e.g. that the requested examination is not available in the patient's home county, or that waiting times or travelling distances are shorter in a neighbouring county. This effect certainly explains some of the differences between Oslo, and the surrounding county of Akershus. However, the merged rate per thousand for these two counties was still high. In many other parts of the country the travel distances are long and inconvenient. Exact information on patient migration in radiology is sparse, but data from one private institution in each of three counties showed that 85%, 95% and 98% of the patients lived in the county where the institution was located [14]. Indirect information is given by the fact that the number of patients who choose to be treated (in general, not limited to radiology) outside their local hospital in 2002 was small [15]. Free choice of hospital was implemented in Norway in 2001. All in all the problem of migration of patients may have caused that the variations found in this study are slightly overestimated.

Variation caused by differences in accessibility
Availability is a well known factor for explaining variation in utilization rates for radiology [16,17], and probably contributes to the high variability of MRI and CT examinations and the strikingly high rates in Oslo (although burdened with some methodological uncertainties) found in this study. The county of Oslo is atypical, since it comprises the city and its suburbs; a highly urbanized area, with short distances to services, with large university hospitals and high availability of new high-technology imaging facilities. All these factors are associated with

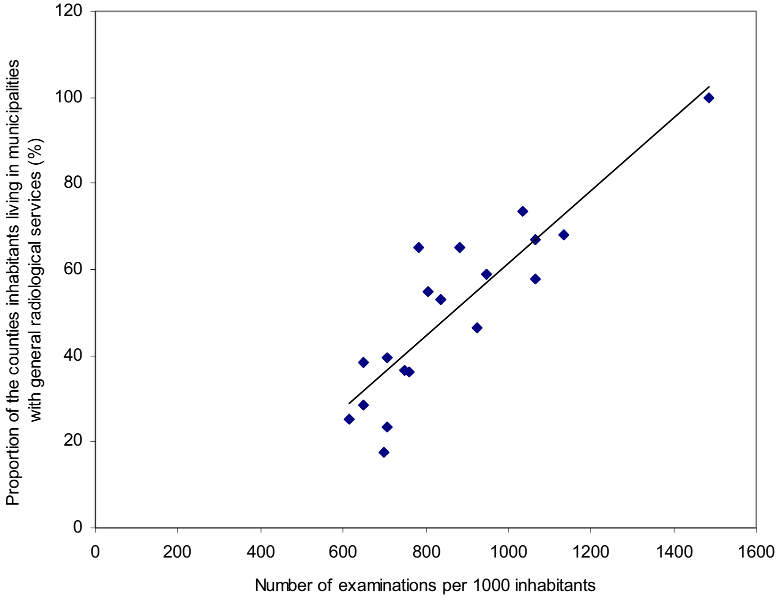

Figure 3
Correlation between the proportion of the counties' population living in municipalities with general radiological services and examination rates per thousand inhabitants. Regression line is displayed.

high use of radiology [1,17]. The radiological institutions in the counties differ in relation to size, the amount of CT and MRI equipment, and maybe also in practice pattern. Aroua [4] found that the rate of chest radiography (a simple examination available "everywhere") was almost three times higher in university hospitals than in small hospitals in Switzerland. Our study also reveals geographical variation in this "low-tech" examination. The acquisition of new technology – which occurs first in larger urban institutions – may lead to additional examinations if (as implied by Olsson [5]) willingness to give up outdated methods varies. This mechanism corresponds well with the correlation that was found between utilization of different modalities for specific organs (locations).

The special position of Oslo was confirmed by the analyses of correlation between different aspects of accessibility and overall examination rates which were markedly influenced by extreme values in this county. It seems somewhat surprising that radiological resources (number of radiologists and radiographers) was not stronger related to examination rates in the other counties. The correlation between examination rates and the proportion of the counties population living in municipalities with radiological services was high even without Oslo's contribution. On this variable the eight counties with lowest score corresponded to the eight with lowest examination rates. In the opposite end of the scale was Østfold and Telemark, in these counties a large proportion of the population lived in municipalities with radiological services, and had correspondingly high examination rates. An interesting difference in examination rates (75%) was found between Telemark and Oppland, two counties with similar population size and radiological resources. Both the population density and the proportion of urban settlement were lower in Oppland than in Telemark, but most noteworthy 68% of the population in Telemark lived in municipalities with radiological services compared with 28% in Oppland. These findings support the importance of proximity to services as explaining factor. One possible interpretation is that in areas with poor access patients (and their GPs) regard the usefulness of the examination as small in relation to the inconvenience (travelling etc) it causes. In this case the necessity of the examination cannot be perceived to be pressing. This interpretation is reasonable in the light of the kind of examinations that vary the most. For example, in cases of knee, shoulder or back pain, which often resolves with time and which does not often represents a severe or life-threatening disease, a "wait and see" approach might be more common if access to radiology is poor.

Other sources of variability

Other frequently stated explanatory factors are socioeconomic differences in the populations [1,16-18] and economic factors [19]. In this study the educational and income level was found to have little impact on examination rates, but these results must be interpreted with caution, as the variations in socioeconomic factors are considered to be higher within than between counties. However, in Oslo the level of education and average income was clearly above mean values in the counties. People with higher socioeconomic status and higher education are presumed to use medical care more readily and to demand more elective services. Ordering an imaging test may be a response to high patient expectation, especially when combined with constrained time resources [20]. In a Norwegian survey, about 50% of the physicians occasionally or often gave priority to patients' wishes over their own medical judgement [21]. Hence, patient pressure is a major factor influencing GPs' referral behaviour. For example, Morgan et al [22] found that patient pressure was the main factor or a significant factor in 46% of knee radiograph referrals. Closely linked to this are two other factors that influence referral decisions: professional uncertainty [1,23] and medico-legal considerations. Kristiansen et al [24] found that the likelihood of having experienced negative reactions from patients was higher among doctors in central Norway.

Economic incentives can affect both the referring and performing physician/institution. The density of GPs is higher in urban areas. How this affects referral patterns when remuneration is based on a per capita component and a fee-for-service component is ambiguous. GPs may compensate for shortage of patients by providing more services to each patient [25]. On the other hand, they might act more in compliance with patients' wishes for radiology, to keep patients on their lists.

Some GPs report that they refer patients to private radiological institutions when the purpose is mostly to satisfy patients' wishes, while in cases of high probability of positive findings they refer to the hospital [23]. They assume that they would have referred fewer patients if private institutions had not been available. This may be because hospitals practise referral guidelines more strictly than private practices, as indicated (in general) by Iversen and Lurås [25]. The finding that the proportion of contribution from private institutions was correlated to the variability in single examinations is interesting in this context. Besides, the kind of examinations for which both the contribution from private institutions and the variability was high fits well into this picture: examinations for which justification is controversial, e.g. knee [22] and spine [26,27], and for which serious disease is seldom revealed. Private radiological institutions are located in the large towns, 1/3 in the city of Oslo. When both private and pubic sectors are established in the same region, it is crucial for the overall radiological activity in the region whether they compete or complement each other. If this is the case is an open question.

The fact that high rates of use do not necessarily improve patient outcome [2,28], raises the question of whether geographical variation in radiological services reflects inappropriate use. Geographical variation in user rates for medical services does not determine the appropriateness of the services [29], in order to determine what constitutes overuse and underuse, data on variation must be linked to information on indications, clinical outcome, risks and costs. Analyses of clinical outcome were far beyond the scope of this study. Neither was it possible to perform quantitative analyses of variation in morbidity as explaining factor for variation in examination rates due to lack of available statistics. The nationwide health survey available are either limited to age groups or specific diagnoses that can not be easily linked to use of radiological services (e.g. cardiovascular disease and diabetes) or they are not representative on the county level. Such analyses could indirectly have illuminated the question of appropriateness of the use of radiological services in the counties. According to Leape et al inappropriate use occurs in low-use areas as well as in high-use areas [30]. Even though, in industrialised countries today, we cannot ignore the problem of patients who are referred too late or not at all [3,29], the problem of unnecessary examinations appears to be more pertinent [22,26,31,32]. Indications of supplementary examinations found in this study, that high use of one modality does not correspond with low use of an alternative modality for specific organs (locations), support the assumption that overuse exists in high-use areas. The lack of a substitution effect of one type of imaging for another has also been found in other studies, i.e. areas with higher rates of one type of imaging also had higher rates of another type [2]. The question of possible overtesting is crucial to address if we want to avoid or to minimise rationing of care to sick patients [33], as radiology is a costly enterprise [32], and overall health care resources are limited. Neglect of this issue leads to a risk of unjust diversion of resources from sick people to people who are worried but healthy.

Conclusion

There was substantial geographical variation in use rates of radiology in Norway, especially for MRI and CT examinations. Accessibility seems to be a plausible explanation, besides socioeconomic factors and the contribution from private institutions may play a part. The study was not designed to verify/disprove overuse or underuse of radiology. However, characteristics of examinations with high variability and indications of supplementary examinations mean that overuse cannot be ruled out, but neither can underuse. We believe that the findings reveal a potential for more equal access to radiological services and for better allocation of overall health care resources.

Competing interests

The author(s) declare that they have no competing interests.

Authors' contributions

IB collected the data. KBL analysed the data and drafted the manuscript. IB and KBL revised and finally approved the manuscript.

Additional material

Additional File 1

Table of settlement characteristics, radiological resources and socioeconomic factors in the counties*. The additional file displays the figures of settlement characteristics, radiological resources and socioeconomic factors in the counties that were used in the analyses. The data source is Statistics Norway [12] except from the number of working radiologists which was obtained from The Norwegian Medical Association (on personal request).*

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[http://www.biomedcentral.com/content/supplementary/1472-6963-7-21-S1.ppt]

Additional File 2

Map of Norwegian counties*. The additional file is a map that displays the location of Norwegian counties.*

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[http://www.biomedcentral.com/content/supplementary/1472-6963-7-21-S2.pdf]

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III

BMC Health Services Research

Research article

What causes increasing and unnecessary use of radiological investigations? a survey of radiologists' perceptions

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Abstract

Background: Growth in use and overuse of diagnostic imaging significantly impacts the quality and costs of health care services. What are the modifiable factors for increasing and unnecessary use of radiological services? Various factors have been indentified, but little is known about their relative impact. Radiologists hold key positions for providing such knowledge. Therefore the purpose of this study was to obtain radiologists' perspective on the causes of increasing and unnecessary use of radiological investigations.

Methods: In a mailed questionnaire radiologist members of the Norwegian Medical Association were asked to rate potential causes of increased investigation volume (fifteen items) and unnecessary investigations (six items), using five-point-scales. Responses were analysed by using summary statistics and Factor Analysis. Associations between variables were determined using Students' t-test, Spearman rank correlation and Chi-Square tests.

Results: The response rate was 70% (374/537). The highest rated causes of increasing use of radiological investigations were: a) new radiological technology, b) peoples' demands, c) clinicians' intolerance for uncertainty, d) expanded clinical indications, and e) availability. 'Over-investigation' and 'insufficient referral information' were reported the most frequent causes of unnecessary investigations. Correlations between causes of increasing and unnecessary radiology use were identified.

Conclusion: In order to manage the growth in radiological imaging and curtail inappropriate investigations, the study findings point to measures that influence the supply and demand of services, specifically to support the decision-making process of physicians.

Background

Utilization of high-technology and high-cost diagnostic imaging has increased substantially over the past decades [1-7]. This growth can be attributed to various factors such as aging populations, advances in imaging technology, that radiology is indicated in more clinical conditions [6,8], availability of the technology [9] and increasing number of radiologists [10]. Referring physicians have a central role in how radiological services are used, and studies have singled out several factors affecting their test-ordering behaviour, including patients' expectations [11-14], professional uncertainty [12,14], stress from uncertainty and time constraints [15], defensive medicine [16,17], payment system [18], and physicians' self-referral [19,20]. The significance of these factors may vary by institutional structures and across countries.

Some of these influences may lead to utilization growth as well as over-utilization [21]. Over-utilization implies wasteful investigations, which according to European Referral guidelines for imaging [22] has the following main causes: repeating investigations, investigations when the results are unlikely to affect patient management, investigating too often, doing the wrong investigation, insufficient clinical information and unclear referral questions, and over-investigation (for reassurance of clinicians and patients). Over-utilization is the main concern among the problems of inappropriate utilization [23].

The expansion of radiological services has a significant impact on health care costs [23,24], the quality of health care services and health care risks [10]. The risk of radiation exposure is drawing increasing attention [25,26]. Because some reasons for expanded use may not benefit patient care, it is crucial to identify the main factors contributing to imaging growth.

Although many influencing factors are known, few studies have explored and quantified their relative impact on the use of diagnostic imaging, and hardly any have studied the subject from the position of those who provide the services. Radiologists are in a key position to illuminate this topic as their perception is refined through experiences with a multitude of referrals, interaction with clinicians and patients, and knowledge of indications for imaging. Their perceptions of the mechanisms behind increased and unnecessary use of radiological investigations can provide important input for managing the growth of imaging and limit over-utilization. The purpose of this study was to obtain radiologists' perception of causes of increasing and unnecessary use of radiological investigations.

Methods

Setting and study population

This was a national survey conducted in Norway, where radiology services are provided by public in-house state-run hospital departments and by private radiology institutes. Both receive public refunds for ambulatory services, and Norway has universal health coverage. (See Additional file 1 for further information). Data on radiologist members were obtained from the Norwegian Medical Association (NMA), where almost all (96.8%) physicians are members [27]. Their lists contain all currently practising members, both approved specialists and registered trainees in radiology (registrars). In February 2007 this totalled 564 physicians (not including those with addresses abroad) who were invited to participate in the survey. The introductory letter to the survey questionnaire informed them of the purpose of the study and the confidential handling of their responses. The study had approval from the Norwegian Social Science Data Services (NSD).

Survey

The questionnaire was constructed after an extensive literature review, as no suitable tool was found. Survey validity was tested by group and individual interviews with radiologists from four different practice settings. This led to changes in content and format and reduced the length of the questionnaire. Further minor adjustments were made based on responses from an anonymous pilot survey sent to 20 physicians randomly selected from the list of 564.

In mid April 2007 the remaining 544 radiologists/registrars in radiology were sent the final questionnaire with an introductory letter and a return envelope with postage paid. Four weeks later, a reminder was sent with a new copy of the questionnaire and a new return envelope. No respondent identifier was applied, hence the reminder was sent to all individuals.

The questionnaire consisted of four parts; this study is based on parts 1 and 4 (see Additional file 2: The original questionnaire). Part 1 contained two questions regarding use of radiological investigations. Question 1 read: "The volume of radiological investigations is increasing in Norway. To what extent do you think this may be caused by the following factors?" Fifteen possible causes (items) were listed. Respondents could also provide additional causes in free-text. Question 2 listed the six main causes of unnecessary use of radiological investigations, as stated in Referral guidelines for imaging [22], and asked "To what extent do you think this occurs at your workplace?" In both questions a five-point response scale (to a very small extent, to a small extent, to some extent, to a large extent, to a very large extent) was used. To ease interpretation and presentation of the distribution of responses, the two responses at each end of the scale were combined in the analyses.

Part 4 of the questionnaire concerned demographic, professional and practice setting characteristics of the respondents. It also contained questions about local access to radiological services (capacity at own workplace, travel time to closest other provider of radiology services).

Data analysis

Descriptive analyses were applied to the entire sample of respondents to examine demographic, professional and practice setting characteristics variables (listed in Additional file 3) by frequencies and proportions. Two variables were dichotomized, partly due to the small number of responses in subcategories: *type of institution employed* into the categories of (public) hospitals and (private) radiological institutes, and *capacity of radiology supply in own practice* into insufficient versus sufficient (which includes free capacity). *Years in radiology practice* was categorized into decades.

Frequencies and proportions were also computed from responses to each item in question 1 and 2. To uncover underlying structure in the set of 15 suggested causes of increased investigation volume (question 1) and identify latent themes among the responses, these 15 items were included in an exploratory factor analysis (extraction method: principal components) with varimax rotation (Direct Oblimin rotation did not show strong correlations between the factors). The number of factors to be extracted was based on the Kaiser rule of eigenvalues of > 1.0. Individual items were included in a factor if the absolute value of their factor loading was ≥ 0.4. Sampling adequacy was assessed by Kaise-Meyer-Olkin (KMO) statistics. Finally, internal reliability of the new factors (i.e. latent variables) was measured using Cronbach alpha. Respondents' factor scores were computed as the sum of weighted item scores (raw score on items included in the latent variable multiplied by the item's factor loading).

Associations between factor scores and demographic, professional or practice setting characteristics were analyzed by T-tests (in dichotomy variables) or Spearman rank correlation. Associations between such characteristics and perceived occurrences of unnecessary use of radiological investigations were analyzed by Chi-Square tests (test for trend, using the 3-point scale) and Spearman rank correlation. Associations were calculated with controls for place of employment of respondents (by analyzing hospital radiologists and institute radiologists separately) as respondents employed in hospitals and radiological institutes differed in other background variables. Spearman rank correlation was also used in analyses of correlations between latent variables involved in increased investigation volume and the six causes of unnecessary investigations. P values of less than 0.05 (two-tailed) were considered statistically significant. Data analyses and statistical tests were performed using SPSS for Windows (version 14.0) software.

Results

The overall response rate was 70% (375 of 537 physicians), 276 responded to the first and 99 to the second mailing. The denominator in the calculation was reduced from 544 to 537 because three physicians informed us that they had not responded due to recent retirement, and four questionnaires were returned due to unknown address.

Respondent demographics and practice information

Eighty-three percent of the respondents were approved specialists in radiology and 57% were men. (The corresponding numbers in the total invited population of 564 radiologists were 83% approved specialists and 59% males.) The mean years in radiology practice was 15.9 years (SD, 10.41 years, ranging from below 1 year to 40 years). The majority of respondents (87%) worked full time in public hospitals (66% in large and 16% in smaller hospitals). The proportion of radiological institute employed radiologists among invited and responders were 9% and 10%, respectively.

One hundred and seventy-two (46%) considered the capacity of radiology supply in their own practice as insufficient, 40% as sufficient and 5% reported free capacity. Travel time to closest other (i.e. neighbour) provider of radiology services was reported to be less than half an hour by 56% of respondents, between half an hour and one hour by 29%, and more than one hour by 9% of respondents.

Perceived causes of increased investigation volume

Table 1 shows the responses given to the fifteen suggested causes of increased volume of radiological investigations. The five highest scored causes were: increased possibilities due to new radiological technology; peoples' increased demands for certain knowledge about own health; referring physicians' lower tolerance for uncertainty; expanded clinical indications for radiology; and increased availability of radiological equipment and personnel. These causes all received high scores (to a large or very large extent) from 50% or more of the respondents, and low scores (to a small or very small extent) from 10% or fewer of the respondents. Free-text was used by 43 of the respondents mainly to elaborate on given causes rather than to add new ones.

Factor analysis of responses to suggested causes of increased investigation volume identified five latent variables that accounted for 60% of the total variance and embraced causes concerning 1) *referring physicians' uncertainty*, 2) *efficiency and economy*, 3) *patients autonomy and legal claims*, 4) *medical possibilities*, and 5) supply and demand of services - *health market* (Table 2). Reliability analyses showed sufficient internal consistency, according to the convention in exploratory research; Cronbach's alpha above 0.6 [28]. The latent variable *health market* showed low internal consistency and included the item increased morbidity in the population, which was weakly and negatively correlated to the variable. When this item was excluded from the variable, Cronbach's alpha

Table 1: Radiologists' ratings of the extent to which suggested causes increase the volume of radiological investigations

Suggested cause	Number (%) of responses		
	To a small or very small extent	To some extent	To a large or very large extent
Increased possibilities due to new radiological technology	2 (0.5)	62 (16.6)	310 (82.9)
Peoples' increased demands for certain knowledge about own health	8 (2.1)	95 (25.4)	271 (72.5)
Referring physicians have less tolerance for uncertainty	16 (4.3)	113 (30.4)	243 (65.3)
Expanded clinical indications for radiology	29 (7.8)	128 (34.4)	215 (57.8)
Increased availability of radiological equipment and personnel	37 (9.9)	142 (37.9)	196 (52.3)
Referring physicians have less competence to perform clinical examinations	54 (14.4)	183 (48.9)	137 (36.6)
Increased risk of litigation against health care providers	72 (19.3)	171 (45.7)	131 (35.0)
Increased demand on health care professionals' effectiveness	97 (26.1)	149 (40.1)	126 (33.9)
Strengthening of patient rights	76 (20.5)	192 (51.8)	103 (27.8)
Referring physicians have less knowledge about accurate use of radiology	90 (24.1)	190 (50.9)	93 (24.9)
Increased demands for documentation from the National Insurance Service or insurance companies	129 (34.7)	167 (44.9)	76 (20.4)
Health service providers' increased competition for patients	174 (46.6)	125 (33.5)	74 (19.8)
People's fascination for technological innovations	189 (50.5)	139 (37.2)	46 (12.3)
Increased focus on economic issues in health care services	213 (57.3)	100 (26.9)	59 (15.9)
Increased morbidity in the population	234 (63.1)	114 (30.7)	23 (6.2)

increased from 0.34 to 0.56, indicating that the variable became more likely to measure one single underlying theme. Hence, the item increased morbidity in the population was left out when calculating respondents' factor scores.

Factor scores (sum of weighted item scores) for these five new latent variables were weakly associated with a few of the recorded demographic, professional and practice setting characteristics. *Health market* (with factor scores ranging from 3.1 to 9.4) was emphasized more by hospital than radiological institute employees and more by full-time than part-time employees with differences in mean factor scores of 0.79 (95% CI: 0.37, 1.21, $P < 0.001$) and 0.69 (95% CI: 0.19, 1.20, $P = 0.008$), respectively. *Health market* was also emphasized more by those considering the capacity of radiology supply in their own practice as sufficient compared to those considering it as insufficient (mean difference 30.7, 95% CI: 10.0, 51.5, $P = 0.004$). Female radiologists had a higher score on *patient autonomy/legal claims* than male radiologists (mean difference 0.39 in factor scores (that ranged from 4.4 to 13.2), 95% CI: 0.08, 0.70, $P = 0.012$). Finally, approved specialists had a higher score on *medical possibilities* than registrars (mean difference of 0.38 in factor scores (that ranged from 3.1 to 7.7), 95% CI: 0.11, 0.65, $P = 0.005$).

Perceived causes of unnecessary investigations

Table 3 shows respondents' opinion on causes for unnecessary investigations at their own workplace. The two most frequent causes reported were over-investigation (because some clinicians tend to rely on investigations more than others and some patients take comfort in being investigated), and insufficient clinical information and unclear questions in the referral. As much as 50% and 42% of respondents reported these two reasons, respectively, to occur to a large or very large extent. The least common cause was doing the wrong investigation; 55% reported this to occur to a small or very small extent.

Compared to hospital radiologist, radiologist in radiological institutes consistently reported lower occurrence of causes of unnecessary investigations; the difference was statistically significant for five of the six causes (Figure 1). Moreover, single causes of unnecessary investigations differed between subgroups of respondents (after controlling for institution employed). Those who reported insufficient capacity of radiology supply in their own practice reported more repeating investigations ($P = 0.003$). Male respondents considered investigation when the anticipated result is unlikely to affect patient management to occur more often than did female respondents ($P = 0.020$). Registrars reported both over-investigation and insufficient referral information to occur more often than did approved specialists ($P = 0.040$ and 0.007, respectively). Finally, reporting insufficient referral information was moderately, negatively correlated to respondents' years in radiology practice ($r = -0.198$, $P < 0.001$).

Causes of increased volume related to causes of unnecessary investigations

Latent variables embracing causes for increased investigation volume were correlated to causes of unnecessary investigations (Table 4). Respondents who considered unnecessary investigations to occur to a larger extent tended to give emphasis to *referring physicians' uncertainty*

Table 2: Factor structure and loadings after varimax-rotation[1] of causes of increased volume of radiological investigations

Suggested Cause	Referring physicians' uncertainty	Economy/efficiency	Patient autonomy/legal claims	Medical possibilities	Health market
Referring physicians have less competence to perform clinical examinations	0.86				
Referring physicians have less knowledge about accurate use of radiology	0.77				
Referring physicians have less tolerance for uncertainty	0.66				
Increased focus on economic issues in health care services		0.76			
Increased demand on health care professionals' effectiveness		0.76			
Increased risk of litigation against health care providers			0.76		
Strengthening of patient rights			0.70		
Increased demands for documentation from the National Insurance Service or insurance companies		0.47	0.60		
People's increased demands for certain knowledge about own health			0.58		
Increased possibilities due to new radiological technology				0.77	
Expanded clinical indications for radiology				0.77	
Health service providers' increased competition for patients					0.69
Increased availability of radiological equipment and personnel					0.62
People's fascination for technological innovations					0.57
Increased morbidity in the population					-0.56
Cronbach's alpha	0.69	0.62	0.61	0.62	0.34
Percentage of variance	18.6%	13.4%	11.1%	9.6%	7.6%

[1]Extraction method: Principal Component Analysis. Only factor loadings greater than 0.4 are displayed.

and *health market* as reasons for increasing investigation volume. The correlations were generally weak, strongest between *referring physicians' uncertainty* and over-investigation (to reassure referring clinician and patients), but they were statically significant for all six listed causes of unnecessary investigations. Emphasizing *medical possibility* tended to be associated with considering occurrence of unnecessary investigation to be less frequent.

Discussion

Previous studies have focused on selected factors' impact on use of radiology [9,11,19,29,30], or were restricted to clinicians' point of view [12,14]. This study gives new information by suggesting how the diversity of causal factors may be ranked and interrelated, and by presenting the radiologists' perspective. The high response rate and the careful completing of the questionnaire (maximum 3% missing values in single items) indicate that radiologists regard the study topic interesting and important. This impression is strengthened by some feedback (comments in the questionnaires' margin) from the respondents. Focus on their opinions may further increase their awareness of the issue and urge them to become more involved in decisions on the use of their services, which may be warranted [23].

Our findings suggest that the most important causes for increased volume of radiological investigations are: expanded medical possibilities (due to new technology and more/wider clinical indications for radiology), peoples' and referring clinicians' increased demand for assurance (regarding knowledge about own/patients' health

Table 3: Radiologists' ratings of the extent to which causes of unnecessary investigations occur at own workplace

	Number (%) of responses[1]		
Cause	To a small or very small extent	To some extent	To a large or very large extent
Over-investigation, because some clinicians tend to rely on investigations more than others and some patients take comfort in being investigated	44 (12.3)	136 (38.1)	177 (49.6)
Insufficient clinical information and unclear questions in the referral	57 (16.0)	149 (41.7)	151 (42.3)
Investigation when the results are unlikely to affect patient management, because the anticipated 'positive' finding is usually irrelevant or because a positive finding is so unlikely	97 (27.7)	156 (44.6)	97 (27.7)
Investigating too often, i.e. before the disease could have progressed or resolved or before the results could influence treatment	99 (27.7)	161 (45.1)	97 (27.2)
Repeating investigations which have already been done	138 (38.9)	184 (51.8)	33 (9.3)
Doing the wrong investigation	195 (54.6)	150 (42.0)	12 (3.4)

[1]Only respondents presently working in radiology were asked this question, reducing the maximum number of respondents to 361.

condition), and availability of services. This is quite consistent with previous studies of selected causal factors. Utilization of radiological investigations is documented to increase with availability of services, i.e. supply of new technology [9] and distance from clinic to radiology facility site [31]. Improvements in imaging technology are reported to account for much of the increase in investigation volume [24]. Radiologists have more intimate knowledge of supply related factors than demand factors. Their perception of the latter is supported by general practitioners who report that "patients have become better informed about their rights as patients, and that they appear increasingly demanding" and that this affect their referral behaviour [32]. Compliance with patients' requests can be motivated by doctor-patient relationship considerations and by clinical uncertainty [33]. Uncertainty of diagnosis/management and patient pressure are reported the two most commonly agreed factors affecting British GPs' referral behaviour [14]. Self-referrals which is reported to be an important causal factor [21] was not included as an item in the study because virtually all diagnostic imaging in Norway are referred from non-radiologist to radiologists, and performed in radiology departments or radiological institutes [4].

Unnecessary investigations were regarded to occur mainly due to over-investigation and insufficient referral information. Causes that radiologists may better control themselves, such as wrong or repeat investigations, were not emphasized. Studies of referral quality confirm the occurrence of insufficient referral information [34-36], though its consequences are, to our knowledge, not quantified. The radiologists' emphasis on over-investigation corresponds well with studies of the general practitioners' reasons for requesting x-rays, where patient reassurance [37] and own uncertainty [38] are among the important influencing factors. Uncertainty can be related to "ordering criteria, anxiety, skills, or possible legal actions" [38]. Excessive testing can result from physicians being uncomfortable with uncertainty [21] and is a common "assurance behaviour" by practitioners of defensive medicine.

The listed causes for unnecessary investigations were reported to occur less frequently by institute radiologists compared to hospital radiologists. This does not mean that unnecessary investigations actually occur less frequent in the institutes, which is not supported by other research[39,40]. Respondents were not asked about actual occurrence, and other factors than the six listed may be relevant. A plausible explanation may be that a larger proportion of the institutes' patients are in the early stages of disease, which may challenge a strict differentiation between appropriate and the inappropriate requests.

The interrelation between responses to the questions of increasing and unnecessary use of radiology bears some implications. First, *medical possibility* tends to be associated with lower rating of unnecessary investigations. This poses a challenge for management of imaging services, as radiologists may perceive the expansion as inevitable and a good thing. Second, *referring physicians' uncertainty* was associated with higher ratings of unnecessary investigations. This supports the hypothesis that radiologists ascribe the main responsibility for unnecessary investigations to the referring clinician. Consequently, the appropriate remedial actions to reduce over-utilization should be to support clinicians in the decision-making process. Clinicians' insufficient knowledge of appropriate use [41] calls for remedial actions from the radiology community [20].

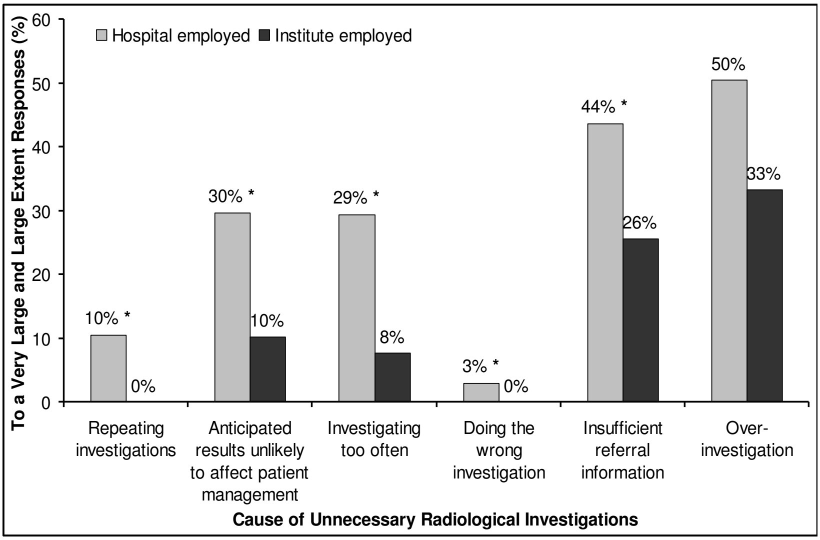

Figure 1
Hospital and institute radiologists' rating of causes of unnecessary investigations. Bar graph illustrates radiologist' employed in hospitals (gray bars) and in institutes (black bars) ratings of the extent to which suggested causes of unnecessary radiological investigations occur. Only the responses to a large extent and to a very large extent are displayed (combined). Difference was statistically significant for four of the causes (p < 0.05, Chi-Square test [asterisks]).

A limitation of this study is that registrars are underrepresented: 17% in the study sample, whereas nearly 30% in the population [42]. This is because registrars do not inform the NMA about their affiliation (A. Taraldset, NMA, personal information). Accordingly, institute radiologists are somewhat over-represented (3 percentage points), as registrars only work in hospitals. However, more registrars and fewer institute radiologists in the study would most likely have strengthened the findings of over-utilization and insufficient referral information as main causes of unnecessary investigations. Generally, the findings should be treated with caution, as comparable studies are lacking.

It is important to note that our findings are only valid in the Norwegian context. The relative impact of factors influencing use of imaging may vary according to differences in health policies, organization of services, and cultural differences. Nevertheless, similarities in utilisation pattern in many developed countries calls for measures to

Table 4: Correlation between suggested causes of unnecessary investigations and factors involved in increased volume of investigations[1]

	Factor involved in increased volume of investigations				
Cause of unnecessary investigations	Referring physicians' uncertainty	Economy/efficiency	Patient autonomy/legal claims	Medical possibility	Health market
Repeating investigations	.220**	-.038	.031	-.066	.239**
Anticipated result unlikely to affect patient management	.321**	.012	.025	-.114*	.179**
Investigating too often	.347**	.029	.016	-.124*	.161**
Doing the wrong investigation	.344**	.018	.039	-.051	.196**
Insufficient referral information	.346**	.092	.035	-.120*	.113*
Over-investigation	.434**	.007	.067	-.090	.196**

[1]Numbers are Spearman Rank Correlation Coefficients.
** P < 0.01, * P < 0.05

improve the use of radiological investigations, and certain causes of increased and inappropriate use may be similar in other countries. Hence, the results from our study may be of international interest, to health care administrators, authorities and health policy makers, as well as clinicians and radiologists. Furthermore, our method may be of relevance for other studies.

Conclusion

According to radiologists' perceptions the most important causes for increased investigation volume are expanded medical possibilities, and supply and demand of services. The latter is also regarded a major cause of unnecessary radiological investigations. This indicates that measures to influence supply and demand of services are important in order to manage growth in investigations volume and reduce unnecessary investigations. Specifically, support to the decision-making process of physicians seems to be important. Further research on factors influencing use of radiology services from the providers' perspective is needed, to confirm, complement or challenge our findings.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

KBL designed the study, collected and analysed the data, and drafted the manuscript. BMH contributed in the design of the study, interpretation of results and in drafting the manuscript. Both authors revised and approved the final manuscript.

Additional material

Additional file 1

Radiology services in Norway*. A brief description of how radiology services are organized in Norway.*
Click here for file
[http://www.biomedcentral.com/content/supplementary/1472-6963-9-155-S1.pdf]

Additional file 2

The questionnaire*. The questionnaire in English translation.*
Click here for file
[http://www.biomedcentral.com/content/supplementary/1472-6963-9-155-S2.pdf]

Additional file 3

Respondents' demographic characteristics and practice information, and some corresponding number in the population*. The additional file is a table that displays the respondents' replies on demographic and practice setting variables. In addition, the available corresponding numbers in the population (564 radiologists) is provided.*
Click here for file
[http://www.biomedcentral.com/content/supplementary/1472-6963-9-155-S3.pdf]

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IV

Appendix A

UNIVERSITETET I OSLO

DET MEDISINSKE FAKULTET

Institutt for allmenn- og samfunnsmedisin
Seksjon for medisinsk etikk
Postboks 1130 Blindern
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Nettadresse: www.med.uio.no/iasam/sme

Kjære radiolog!

16.april 2007

Undersøkelse om radiologers oppfatninger omkring bruk av bildediagnostikk

Beslutninger om hvilke radiologiske undersøkelser som skal utføres kan være vanskelige og påvirkes av mange faktorer. I forskningslitteraturen beskrives ulike hensyn som spiller inn når leger vurderer om pasienten skal henvises til radiologisk undersøkelse, det gis også mange forklaringer på hvorfor omfanget av radiologiske undersøkelser er stigende. Derimot mangler vi kunnskap om hvordan radiologer oppfatter at tjenesten brukes, hvordan dere deltar i beslutninger om hvilke undersøkelser som skal utføres, og generelt hvordan dere oppfatter radiologifagets og egen profesjons rolle i helsevesenet. Dette prosjektets formål er å undersøke disse spørsmålene.

Radiologers oppfatninger er viktige fordi spørsmålet om hvordan radiologitjenesten brukes direkte angår deres arbeidshverdag. Dessuten er det er dere som har førstehåndskunnskap til hvordan tjenesten brukes. Arbeidet med optimalisering av bruken av radiologi er derfor avhengig av innspill fra dere. Vi ber deg derfor om å avsette anslagsvis **10 minutter** til å bidra med dine kunnskaper, erfaringer og synspunkter ved å besvare vedlagt spørreskjema. Svarfristen er **7. mai -07**.

Styret i **Norsk Radiologisk Forening** har gitt sin støtte til prosjektet og har godkjent undersøkelsen, som inngår i Kristin Bakke Lysdahls doktorgradsarbeid ved Institutt for allmenn- og samfunnsmedisin, Universitet i Oslo. Utarbeidelsen av spørreskjemaet har foregått i godt samarbeid med flere av dine kollegaer og med kyndig veiledning fra Legeforeningens forskningsinstitutt. Enkelte korreksjoner er også utført på bakgrunn av en nylig gjennomført pilotundersøkelse. Har du spørsmål eller kommentarer vedrørende spørreskjemaet kan du gjerne ta kontakt via e-post Kristin.Bakke@medisin.uio.no eller direktetelefonnummer 22 84 46 49.

Spørreskjemaet er sendt til alle yrkesaktive radiologer som er medlemmer av Den Norske Lægeforening. Undersøkelsen er anonym, og alle svar vil bli behandlet konfidensielt. Dersom entydig personidentifisering er mulig ut fra kombinasjon av bakgrunnsopplysninger vil omkoding foretas ved prosjektets avslutning (utgangen av 2008). Studien er meldt til Personvernombudet for forskning, Norsk samfunnsvitenskapelig datatjeneste AS.

Med vennlig hilsen

Bjørn Hofmann	Kristin Bakke Lysdahl
Professor II	Høgskolelektor, stipendiat

Appendix B

A Bruk av radiologiske undersøkelser

1 Omfanget av radiologiske undersøkelser er økende i Norge. I hvilken grad mener du dette kan skyldes følgende faktorer?

		I svært liten grad	I liten grad	I noen grad	I stor grad	I svært stor grad
a	Økt sykelighet i befolkningen	☐	☐	☐	☐	☐
b	Styrkning av pasienters rettigheter	☐	☐	☐	☐	☐
c	Befolkningen stiller økte krav til sikker kunnskap om egen helse	☐	☐	☐	☐	☐
d	Lavere toleranse for usikkerhet hos henvisende leger	☐	☐	☐	☐	☐
e	Lavere kompetanse hos leger i å utføre kliniske undersøkelser	☐	☐	☐	☐	☐
f	Økte muligheter ved ny radiologisk teknologi	☐	☐	☐	☐	☐
g	Utvidede kliniske indikasjoner for radiologi	☐	☐	☐	☐	☐
h	Mindre kunnskap om riktig bruk av radiologi hos rekvirenter	☐	☐	☐	☐	☐
i	Befolkningens fascinasjon over teknologiske nyvinninger	☐	☐	☐	☐	☐
j	Økt tilgjengelighet av radiologisk utstyr og personell	☐	☐	☐	☐	☐
k	Økte effektivitetskrav til helsearbeidere	☐	☐	☐	☐	☐
l	Økt fokus på økonomi i helsevesenet	☐	☐	☐	☐	☐
m	Økt konkurranse om pasientene i helsevesenet	☐	☐	☐	☐	☐
n	Økte dokumentasjonskrav fra trygdevesen/forsikringsselskap	☐	☐	☐	☐	☐
o	Økt risiko for juridiske søksmål mot helsevesenet	☐	☐	☐	☐	☐
p	Annet, spesifiser: ______________________________	☐	☐	☐	☐	☐

____

Hvis du for tiden ikke praktiserer som radiolog, vennligst gå direkte til spørsmål 9

2 Listen nedenfor viser hovedårsakene til unødvendig bruk av radiologiske undersøkelser. **(Hentet fra: "Hensiktsmessig bruk av en radiologisk avdeling. Retningslinjer for leger" europeiske retningslinjer i norsk oversettelse).** **I hvilken grad mener du dette forekommer ved din arbeidsplass?**

		I svært liten grad	I liten grad	I noen grad	I stor grad	I svært stor grad
a	Gjentagelse av undersøkelser som allerede er utført	☐	☐	☐	☐	☐
b	Undersøkelser der det er usannsynlig at resultatet får konsekvenser for behandlingen av pasienten, fordi det forventede "positive" funn oftest er irrelevant eller fordi positivt funn er så usannsynlig	☐	☐	☐	☐	☐
c	Det undersøkes for ofte, dvs. før sykdommen kan ha progrediert eller gått tilbake eller før resultatet kan påvirke behandlingen	☐	☐	☐	☐	☐
d	Feil undersøkelse utføres	☐	☐	☐	☐	☐
e	Mangelfulle kliniske opplysninger og uklare spørsmålsstillinger i henvisningen	☐	☐	☐	☐	☐
f	Overundersøkelse, fordi noen leger tenderer til å støtte seg mer til undersøkelser enn andre og noen pasienter føler trygghet/trøst ved å bli undersøkt	☐	☐	☐	☐	☐

B Deltagelse i beslutningsprosessen

3 Hvor ofte får du spørsmål eller blir bedt om råd med hensyn til undersøkelsesvalg?

		Daglig	Ukent-lig	Måned-lig	Sjeldnere enn månedlig
a	Fra henvisende lege	☐	☐	☐	☐
b	Fra pasienter	☐	☐	☐	☐

		Ja, ofte	Ja, av og til	Nei, sjelden	Nei, aldri
4	**Viser du til "Hensiktsmessig bruk av en radiologisk avdeling. Retningslinjer for leger" når du gir råd om undersøkelsesvalg?**	☐	☐	☐	☐

5 Gitt at uklare indikasjoner eller uegnede undersøkelses-/modalitetsvalg i henvisningene forekommer. Hvor ofte foretar du følgende handlinger?

		Daglig	Ukent-lig	Måned-lig	Sjeldnere enn månedlig
a	Jeg sjekker prøvesvar og/eller innhenter opplysninger fra	☐	☐	☐	☐
b	Jeg kontakter henvisende leger for avklaring av spørsmålsstillinger	☐	☐	☐	☐
c	Jeg innhenter supplerende informasjon fra pasienter	☐	☐	☐	☐
d	Jeg utfører kliniske undersøkelser av pasienter	☐	☐	☐	☐
e	Jeg endrer teknikk/modalitet uten å kontakte henvisere	☐	☐	☐	☐
f	Jeg returnerer henvisninger og oppgir begrunnelser for dette	☐	☐	☐	☐
g	Annet, spesifiser: ____________________	☐	☐	☐	☐

____

6 Gitt at du betviler nytten av en rekvirert undersøkelse. I hvilken grad vil faktorene nedenfor bidra til at du forhindrer at den utføres slik som rekvirert?

		I svært liten grad	I liten grad	I noen grad	I stor grad	I svært stor grad
a	Pasienten er ung (barn, ungdom)	☐	☐	☐	☐	☐
b	Pasienten/pårørende ønsker ikke undersøkelsen	☐	☐	☐	☐	☐
c	Undersøkelsen er ubehaglig eller belastende for pasienten	☐	☐	☐	☐	☐
d	Stor risiko for alvorlige komplikasjoner eller bivirkninger	☐	☐	☐	☐	☐
e	Undersøkelsen er ressurskrevende (tid eller penger)	☐	☐	☐	☐	☐
f	Henviseren er åpen for veiledning	☐	☐	☐	☐	☐
g	Høy stråledose ved undersøkelsen	☐	☐	☐	☐	☐
h	Stor risiko for falske positive/negative funn	☐	☐	☐	☐	☐
i	Radiografen stiller spørsmål ved henvisingen	☐	☐	☐	☐	☐
j	At radiologarbeidet skal oppleves meningsfullt	☐	☐	☐	☐	☐
k	Annet, spesifiser: ____________________	☐	☐	☐	☐	☐

____

7 **Gitt at du betviler nytten av en rekvirert undersøkelse. I hvilken grad vil faktorene nedenfor bidra til at undersøkelsen likevel utføres slik som rekvirert?**

		I svært liten grad	I liten grad	I noen grad	I stor grad	I svært stor grad
a	Pasienten/pårørende ønsker undersøkelsen	☐	☐	☐	☐	☐
b	Pasienten er allerede ankommet	☐	☐	☐	☐	☐
c	Stor faglig respekt for henviserens vurdering	☐	☐	☐	☐	☐
d	Henviseren er vanskelig tilgjengelig	☐	☐	☐	☐	☐
e	Retningslinjer for bruk av undersøkelsen er uklare	☐	☐	☐	☐	☐
f	Høy refusjon for undersøkelsen	☐	☐	☐	☐	☐
g	Frykt for rettslig etterspill	☐	☐	☐	☐	☐
h	Tidspress	☐	☐	☐	☐	☐
i	Produktivitetskrav på arbeidsplassen	☐	☐	☐	☐	☐
j	Annet, spesifiser: ______________________	☐	☐	☐	☐	☐

____

8 **Er det praktiske prosedyrer eller organisatoriske forhold ved din arbeidsplass som forhindrer deg fra å påvirke beslutninger om hvilke undersøkelser som skal gjennomføres?**

____

____

C Rolleoppfatning

9 **Nedenfor følger noen påstander omkring radiologi og radiologer generelt. I hvilken grad er du enig eller uenig i disse?**

		Helt enig	Delvis enig	Nøytral	Delvis uenig	Helt uenig
a	Radiologi er et velegnet middel til å berolige engstelige pasienter	☐	☐	☐	☐	☐
b	Pasienter forventer at radiologen involverer seg i deres helhetlige kliniske situasjon	☐	☐	☐	☐	☐
c	Stråledoser fra radiologi kan trolig motvirke kreftutvikling	☐	☐	☐	☐	☐
d	Høy kvalitet på radiologiske undersøkelser forutsetter klart spesifiserte problemstillinger	☐	☐	☐	☐	☐
e	Radiologi bør i større grad inngå i vanlige helsekontroller	☐	☐	☐	☐	☐
f	Radiologer oppnår faglig respekt når de går i aktiv dialog med klinikere og veileder dem i bruk av radiologi	☐	☐	☐	☐	☐
g	Pasientens tillit til sin lege rokkes dersom radiologen stiller spørsmål ved henvisningen	☐	☐	☐	☐	☐
h	I henvisningene bør leger begrense seg til å gi klare problem-stillinger, og ikke be om bestemte undersøkelser	☐	☐	☐	☐	☐
i	Radiologer må akseptere at det er andre grunner enn de rent medisinske til at pasienten og henviser ønsker undersøkelser	☐	☐	☐	☐	☐
j	Radiologer har delansvar for å begrense Norges helsekostnader	☐	☐	☐	☐	☐
k	Liberal bruk av radiologi er oftest kostnadseffektivt	☐	☐	☐	☐	☐
l	Prioritering ut fra alvorlighetsgrad, utbytte og kostnadseffektivitet er mest relevant ved behandling, i mindre grad ved diagnostikk	☐	☐	☐	☐	☐

10 Unødvendig bruk av radiologiske undersøkelser kan ha negative konsekvenser. I hvilken grad oppfatter du konsekvensene nedenfor som etisk utfordrende?

		I svært liten grad	I liten grad	I noen grad	I stor grad	I svært stor grad
a	Redusert tilgang til radiologi for andre pasienter	☐	☐	☐	☐	☐
b	Mindre ressurser til andre helsetjenester	☐	☐	☐	☐	☐
c	Unødvendig stråledose til pasienter	☐	☐	☐	☐	☐
d	Unødvendig risiko for falske positive funn med oppfølgingsbehov	☐	☐	☐	☐	☐
e	Skader radiologers faglige selvrespekt (integritet)	☐	☐	☐	☐	☐
f	Annet, spesifiser: ______________________	☐	☐	☐	☐	☐

____

D Bakgrunnsopplysninger

11 Kjønn Kvinne ☐ Mann ☐

12 Er du godkjent spesialist i radiologi? Ja ☐ Nei ☐

13 Subspesialitet/hovedarbeidsområde (vennligst kryss kun av på ett av alternativene):

Angio/inter-vensjon	Barne-radiologi	Nevro-radiologi	CT	MR	Ultralyd	Mammo-grafi	Generell radiologi	Annen eller tilleggs-subspesialitet/hovedarbeidsområde:
☐	☐	☐	☐	☐	☐	☐	☐	______________

14 I hvor mange år har du arbeidet som radiolog? ☐

De resterende spørsmålene gjelder bare deg som for tiden praktiserer som radiolog

15 I hvor stor stillingsandel er du tilsatt som radiolog? ____ %

16 Hvor stor del av din stilling er evt. avsatt til annet enn pasientrettet arbeid (f.eks. forskning, undervisning, administrasjon o.a.)? ____ %

17 Ved hvilke type institusjon har du ditt daglige arbeid?

Stort offentlig sykehus (universitetssykehus eller tidligere regions-/sentralsykehus) ☐

Mindre offentlig sykehus (tidligere lokalsykehus/mindre fylkessykehus) ☐

Røntgeninstitutt ☐

Annet, spesifiser: ______________________ ☐

18 Hvordan er kapasiteten på radiologitilbudet innen ditt fagområde på ditt arbeidssted?

Det er ledig kapasitet til å ta imot flere pasienter ☐

Det er tilstrekkelig kapasitet i forhold til pasientgrunnlaget ☐

Det er mangelfull kapasitet med lange ventetider for pasientene ☐

19 Hvor lang reisetid er det fra din arbeidsplass til nærmeste andre radiologienheten? Ca. ________ time(r)

Tusen takk for dine svar!